Retrospective analysis of long-term speech performance in cochlear implant recipients using electro-acoustic stimulation

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1.0 Synopsis

Study Title	Retrospective analysis of long-term speech performance in cochlear implant recipients using electro-acoustic stimulation
Sponsor	Advanced Bionics AG
Investigational Device	Naída CI M and Naída CI Q and associated acoustic earhooks
Study Design	A monocentric observational post-market clinical follow-up study (PMCF) based on a retrospective data analysis of anonymized clinical data
Study Population	All subjects fulfilling inclusion and exclusion criteria and registered in clinical patient database at the time of the extraction of the data
Inclusion Criteria	Being implanted with Ultra or Ultra 3D SlimJ Being a user of the "acoustic earhook" system Having provided informed consent regarding use of his/her data for research
Exclusion Criteria	N/A
Primary Study/Efficacy Objective	Mean monosyllabic word recognition score with the EAS system in quiet at twelve months after first fitting of 30% or better
Primary Study/Efficacy Endpoint	Group average on the Freiburger Monosyllabic Word Test (in quiet) of 30% or more at twelve-month after first fitting
Secondary Study/Efficacy Objective	Mean sentence recognition score with the EAS system in quiet at twelve months after first fitting of 40% or better
Secondary Study/Efficacy Endpoint	Group average in the HSM sentence test (in quiet) of 40% or more at twelve-month after first fitting
Safety Objective	N/A
PMCF Objective (if required)	Collection of additional clinical data on acoustic earhook performance
Study Schedule & Duration	Estimated time for data collection, analysis and writing of the report: 3 months

2.0 Glossary and Abbreviations

(S)AE	(Serious) Adverse Event
BTE	Behind-the-ear
CIP	Clinical Investigation Plan
CPI	Clinician Programming Interface
CRF	Case Report Forms
dB	Decibel
EAS	Electro Acoustic Stimulation
EC	Ethics Committee
HA	Hearing Aid
ICF	Informed Consent Form
ICS	Implantable Cochlear Stimulator
IRB	Institutional Review Board
SNHL	Sensorineural hearing loss
SNR	Signal-to-noise ratio
SPL	Sound Pressure Level

3.0 Background and Purpose of the Investigation

Some subjects who have had a cochlear implant retain some residual aidable hearing, using a specific accessory called an acoustic earhook. This device provides acoustic stimulation just as a hearing aid would do, in addition to the electrical stimulation provided by the implant. The aim of the study is to collect data on the use of the acoustic earhook. This suggests that there is an interest in understanding how this accessory is used by patients after implantation.

This clinical study will be conducted to assess, within the scope of its intended purpose, devices which bear the CE mark and where the investigation would not involve submitting subjects to procedures additional to those performed under the normal conditions of use, per MDR (EU) 2017/745 Article 82.

4.0 Investigational Device Description

4.1 Manufacturer details

Manufacturer details and authorized EU representative are detailed in the following tables (Table 1, Table 2).

Table 1 - Manufacturer contact details

Device	Naída CI M and accessories	Naída CI Q and accessories
Legal manufacturer name	Advanced Bionics, LLC	Currently, Advanced Bionics, LLC At the time the subject received their sound processor, Advanced Bionics AG was the legal manufacturer.
Address	28515 Westinghouse Place, Valencia, CA 91355, USA	Laubisrütistrasse 28, 8712 Stäfa, Switzerland
SRN	US-MF-000019344	N/A
PRRC	[redacted]	N/A
E-mail	[redacted]	N/A
Phone	[redacted]	N/A

Table 2 - Authorized Representative contact details

Authorized representative	Advanced Bionics GmbH
Address	Feodor-Lynen-Strasse 35, D-30625 Hannover, Germany
SRN	DE-AR-000005642
PRRC	[redacted]
E-mail	[redacted]
Phone	[redacted]

4.2 Device identification

Devices under investigation are identified in the table below (Table 3).

Table 3 - Devices identification

Model Number	Sales Description	Basic UDI-DI
CI-5280-xxx	Naída CI Q90	08400944CI5280Y5
Cl-5850-xxx	Naída Cl Q90 Acoustic Earhook	08400944CI5850YS
CI-5293-xxx	Naída CI M90 Sound Processor	08400944CI5293YE
CI-5295-xxx	Sky CI M90 Sound Processor	08400944CI5295YJ
CI-5851-xxx	M Acoustic Earhook	08400944CI5851YU

-xxx specify models for color/size

4.3 General description

4.3.1 General Description of a Cochlear Implant (CI) System

A cochlear implant system consists of:

- Internal components - Implantable cochlear stimulator (or 'implant')
- External components - Sound processor with cables, headpiece, earhook, batteries etc.
- Software - Fitting software, remote application.

4.3.2 Description of Implantable Cochlear Stimulator (ICS)

The internal component or implant includes a receiver and an electrode which are both implanted surgically under the skin behind the ear.

The implant electronics are contained within a hermetically sealed titanium case with a removable magnet and telemetry coil (RF antenna) attached and encased in silicone. The antenna coil assembly receives power and data over an inductively coupled link from the external sound processor system. The electrode consists of a fantail, electrode lead, and electrode array. Figure 1 illustrates the ICS.

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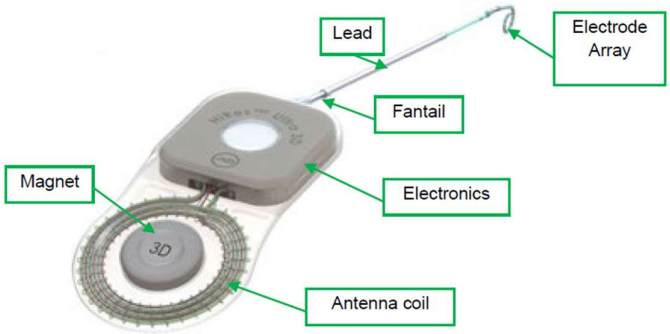

Figure 1 1: Example of a cochlear implant: HiRes™ Ultra 3D CI with HiFocus™ Mid-Scala electrode

The HiFocus SlimJ electrode consists of an electrode lead and electrode array. The electrode contacts are housed in a silicone carrier, referred to as the electrode array. The wires, composed of platinum-iridium alloy, are housed in a silicone carrier, referred to as the electrode lead, and extend from the titanium case of the HiRes Ultra or Ultra 3D.

The HiFocus SlimJ electrode is approximately 23 mm in length (from blue marker to distal tip) and is designed to be inserted approximately 420° into a normal patient cochlea (Figure 2) The array consists of 16 planar contacts arranged along the medial (inside) surface of the electrode array for stimulation of discrete segments of the cochlea. The electrode contacts are numbered 1 through 16 from apex to base, and spaced so that the contacts fall in similar locations in the cochlea as with the HiFocus Mid-Scala electrode. There is one blue marker on the electrode array, positioned proximal to the 16th contact and placed adjacent to a raised feature on the electrode silicone carrier. The total electrode lead and fantail length is approx. 77.6 mm. This includes the distal, thin portion of the lead up to the 'wing' feature, which allows for better visualization during electrode array implantation.

The SlimJ electrode can be inserted using a free-hand technique using the Forceps and the HiFocus Mid-Scala electrode reusable metal tools, which includes two identical cochleostomy recess gauges and two identical claw tools.

Figure 2 : HiFocus SlimJ Electrode

4.3.3 Description of external components

- **Sound processor**

The sound processor is available in two functionally similar configurations: off-ear (body-worn) and behind-the-ear (BTE). All sound processors and headpieces function as follows: soundwaves in the environment are captured through the microphone located on the processor, in the headpiece, T-Mic or auxiliary input devices. The processor then converts this sound information into a digital signal that is transferred through the headpiece to the implant. The headpiece contains a magnet which couples with the implant's magnet to keep the headpiece in place over the implant.

- **Headpiece**

The headpiece contains an omni-directional microphone which picks up sounds. The sound signal is passed down the headpiece cable to the sound processor, which analyzes the sound and converts it to a digital signal. The signal is sent back along the headpiece cable to the headpiece, where it is sent transcutaneously to the implant. Figure 3 provides an example of the external components (sound processor, battery) and some accessories (cable, headpiece, microphones)

Figure 3 : Example of the external components of a cochlear implant system

4.3.4 Description of Software

The Programming Software system consists of a standard personal computer running Microsoft Windows with approved Advanced Bionics fitting software and Clinician Programming Interface (CPI). An audiologist or other trained health professional uses the fitting software to set parameters in a strategy to tailor a program for a specific recipient. System diagnostic functions of the system are also available in the software. The CPI provides a bridge between the computer and the sound processor.

4.4 Device Specific description

Marvel (Naída CI M) and Naída CI Q sound processors series uses the same Acoustic Earhook, there is no clinical difference between the devices so no distinction will be made hereafter in this clinical investigation plan (CIP).

The description and specifications of the devices used in this study are detailed in the table below (Table 4).

Table 4 : Device Description and Specification

General description of the device		
CI-5280-xxx - Naída CI Q90	Naída CI sound processors are behind-the-ear (BTE) sound processors that convert sound picked up by the microphone into electrical signals that are used by the cochlear implant to enable hearing. Naida CI sound processor is comprised of the components pictured below. They offer multiple power options and wearing options for the user. The system is designed to provide useful hearing to individuals with severe-to-profound hearing loss.	
CI-5850-xxx - Naída CI Q90 Acoustic Earhook	The Naida CI Q90 Acoustic Earhook allows for the addition of acoustic amplification to the electrical stimulation traditionally produced by a cochlear implant. The Acoustic Earhook attaches to the Naida CI Q90 Sound Processor with the processor connector. From the processor connector, a tube extends to the xReceiver Unit that transfers sound inputs through the sound outlet into the ear's auditory canal. The Acoustic Earhook contains a dash on the side of the xReceiver Unit, that acts as a guide for the loop of the optional Retention Hook, and a colored indicator on the xReceiver Unit, blue for the left ear and red for the right ear.	
CI-5293-xxx (Naída CI M90) CI-5295-xxx (Sky CI M90)	The Marvel CI sound processors (Naída CI M90, and Sky CI M90) are BTE sound processors for use with an Advanced Bionics cochlear implant. The sound processors feature direct connectivity to wireless accessories and Bluetooth® technology enabled devices. They offer multiple power options and wearing options for the user. The system is designed to provide useful hearing to individuals with severe-to-profound hearing loss. The Marvel CI sound processors are behind-the-ear sound processors available as three variants: the Naída CI M90 ("premium" offering), the Naída CI M30 ("essential" offering), and the Sky CI M90 (pediatric offering). The hardware is identical across the three variants, with access to different software features controlled by the firmware resident on the processor.	

CI-5851-xxx (M Acoustic Earhook)	The M Acoustic Earhook is an attachment to the Advanced Bionics Naída CI M90 and Sky CI M90 sound processors. The M Acoustic Earhook allows for the addition of acoustic amplification to the electrical stimulation traditionally produced by a cochlear implant. From the sound processor connector, a cable extends to the speaker unit that transfers sound inputs through the sound outlet into the ear canal. There are 5 sizes of the M Acoustic Earhook for right and left ears to accommodate different ear sizes and shapes. Domes attach to the speaker unit of the acoustic earhook to provide a comfortable fit in the ear canal. The connector pins and pin removal tool are also included.	
Intended use		
CI-5280-xxx - Naída CI Q90	The Naida CI sound processors are accessories of an auditory active implantable system, the HiResolution™ Bionic Ear system. The HiResolution™ Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss.	
CI-5850-xxx - Naída CI Q90 Acoustic Earhook	The Naida Q90 Acoustic Earhook provides acoustic amplification for patients with aidable low frequency hearing.	
CI-5293-xxx (Naída CI M90) CI-5295-xxx (Sky CI M90)	The Naída™ CI M90 sound processor is a behind the ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing. The Naída CI M90 is the premium version with full access to multiple automatic programs and features including bimodal and bilateral and supports compatibility with acoustic amplification. The Sky CI M90 sound processor can be used by both adults and children and provides dedicated pediatric hearing solution (multiple color options, and adjustable program for individual pediatric users). The Sky CI M90 provides full access to multiple automatic programs and features including bimodal and bilateral and supports compatibility with acoustic amplification.	
CI-5851-xxx (M Acoustic Earhook)	The M Acoustic Earhook provides acoustic amplification for patients with aidable low frequency hearing. The M Acoustic Earhook coupled with the Naída CI M90 or Sky CI M90 sound processor is intended to provide acoustic amplification and electrical stimulation to Advanced Bionics cochlear implant recipients.	
Intended use environment		
CI-5280-xxx - Naída CI Q90	The Naida Q sound processor system is intended for use in healthcare and home environments. The home environment is extended to include use outdoors and during travel (e.g., airplanes). The Naída Q sound processor system is intended to operate with the SoundWave fitting software, and with Phonak RemoteMic, DECT Phone, Roger, TVLink II, MyPilot control devices or ComPilot devices used for audio streaming. The user is responsible for security of connections with other devices, including pairing the sound processor with other devices in a secure environment.	
CI-5850-xxx - Naída CI Q90 Acoustic Earhook	The intended use environments of the Naida Q90 Acoustic Earhook are healthcare and daily living environments. The Naida Q90 Acoustic Earhook, are designed to be worn daily during the user's normal waking hours.	

CI-5293-xxx (Naída CI M90) CI-5295-xxx (Sky CI M90)	The intended use environments of the Marvel CI sound processors are healthcare and daily living environments. They are designed to be worn daily during the user's normal waking hours
CI-5851-xxx (M Acoustic Earhook)	The intended use environments of the M Acoustic Earhook are healthcare and daily living environments. The M Acoustic Earhook are designed to be worn daily on the skin over the implant during the user's normal waking hours.
Intended users	
CI-5280-xxx - Naída CI Q90	The intended users of the Naída CI Sound Processors are recipients of Advanced Bionics cochlear implants, their caregivers if applicable, and hearing care professionals. The recipient, or their caregiver, should, at a minimum, be capable of changing the battery, connecting the earhook, placing and removing the sound processor from their ear, and placing and removing the headpiece from the implant site. The hearing care professional should be trained in the use and fitting of the cochlear implant system.
CI-5850-xxx - Naída CI Q90 Acoustic Earhook	The intended users of the Naida Q90 Acoustic Earhook are users of the Naida CI Sound Processors, their caregivers if applicable, and hearing care professionals. The recipient, or their caregiver, should, at a minimum, be capable of changing the battery, connecting the earhook, placing and removing the sound processor from their ear, and placing and removing the headpiece from the implant site. The hearing care professional should be trained in the use and fitting of the cochlear implant system.
CI-5293-xxx (Naída CI M90) CI-5295-xxx (Sky CI M90)	The intended users of the Marvel CI sound processors are recipients of Advanced Bionics cochlear implants, their caregivers if applicable, and hearing care professionals. The recipient, or their caregiver, should, at a minimum, be capable of changing the battery, connecting the earhook, placing and removing the sound processor from their ear, and placing and removing the headpiece from the implant site. The hearing care professional should be trained in the use and fitting of the cochlear implant system.
CI-5851-xxx (M Acoustic Earhook)	The intended users of the M Acoustic Earhook are recipients of the Neptune, Naída CI Q, Naída CI M, or Sky CI M sound processors, their caregivers if applicable, and hearing care professionals. The recipient, or their caregiver, should, at a minimum, be capable of changing the battery, connecting the earhook, placing and removing the sound processor from their ear, and placing and removing the headpiece from the implant site. The hearing care professional should be trained in the use and fitting of the cochlear implant system.
Intended patient population	
Adults – 18 years of age or older Children – 12 months through 17 years of age	
Medical condition(s)	
Information on the clinical condition *The clinical condition of relevance is sensorineural hearing loss, a condition affecting the ability of the inner ear to process and pass auditory information to the brain. This is different from a conductive hearing loss, resulting from physical obstruction or mechanical failure delivering the signal to the inner ear. The most common type of permanent hearing loss is sensorineural hearing loss (it is the cause of more than ninety percent (90%)[1] of hearing loss in adults).* *Sensorineural hearing loss is categorized by frequency (low to high) and by degree (mild, moderate, severe, or profound). The World Health Organization (WHO) documentation describes disabling hearing as a loss of 40 dB or greater (moderate hearing loss), indicating that this degree of hearing loss affects the person's ability to function normally. The onset of hearing loss can be congenital or acquired, sudden or progressive, in one ear or both, and can vary in degree from low to high frequencies. Leading causes of sensorineural hearing loss include inherited disorders, noise exposure, and presbycusis (hearing loss due to normal aging)[2]. With greater the degrees of sensorineural hearing loss, less benefit is provided by amplifying the sound through devices such as a hearing aid. This results in degraded awareness, understanding, and can negatively impact interactions with others.*	

Untreated hearing loss can negatively impact cortical development, speech and language acquisition, environmental awareness, stress, and even cognitive health. Appropriate diagnosis and intervention can help to minimize the impact of hearing loss.

Prevalence of the condition

WHO estimates that 466 million people (6% of the global population) have disabling hearing loss. It is estimated that by 2050 over 900 million people will have disabling hearing loss. The Center for Disease Control reports a prevalence of hearing loss of approximately 0.1% in children. The National Institute on Deafness and Communication Disorders estimates this to be a bit higher at 0.2% or 0.3%. They report about 2% of adults aged 45-54 have disabling hearing loss. The rate increases to 8.5% for adults 55-64. Nearly 25% in adults 65-74 and as high as 50% for those 75 and older[3].

Natural course of the condition

Sensorineural hearing loss occurs in response to a number of factors, with variable time course, severity, and configuration. Hearing loss can manifest at birth (congenital) or begin later in life. It can be severe at onset or progress gradually over time. It can be associated with known factors like genetics, syndromes, comorbidities (diabetes, stroke, tumor) or events (trauma, noise exposure). It can affect one or both ears. The degree of hearing loss can even change by frequency, allowing audibility of low pitch sounds but not high pitch sounds.

Several studies have documented the impact of untreated hearing loss. An often-cited survey was commissioned by the National Council on Aging in 1999[4]. This nationwide survey of nearly 4,000 adults with hearing loss and their significant others showed significantly higher rates of depression, anxiety, and other psychosocial disorders in individuals with hearing loss who were not wearing hearing aids. These findings were consistent with the findings of a large randomized controlled study which found that hearing loss was associated with decreased social/emotional, communication, and cognitive function in addition to increased depression for subjects who were unaided as compared to those who received hearing aids[5].

More recently, Dr. Frank Lin and his colleagues at Johns Hopkins University found a strong link between degree of hearing loss and risk of developing dementia. Individuals with mild hearing loss were twice as likely to develop dementia as those with normal hearing, those with moderate hearing loss were three times more likely, and those with severe hearing loss had five times the risk. While this study could not definitively conclude that early treatment with hearing aids would reduce the risk of dementia, there was a positive correlation between degree of hearing loss and risk of dementia[6].

A WHO report on the global costs of unaddressed hearing loss points to significant costs to the educational sector ($3.9 billion), productivity ($105 billion), and society ($573 billion) per year[7]. They conclude that hearing aids and cochlear implants are a cost-effective strategy in treatment of hearing loss.

References

1. *Deafness and hearing loss. (n.d.). Retrieved October 24, 2020, from https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss*

2. Isaacson, J. E., & Vora, N. M. (2003). Differential diagnosis and treatment of hearing loss. American family physician, 68(6), 1125–1132. Tyagi, Rout: A Revolutionary Treatment of Sensorineural Hearing Loss, 2019, ResearchGate

3. US National institute for deafness and other communication disorders - Based on calculations performed by NIDCD Epidemiology and Statistics Program staff: (1) using data from the 1999-2010 National Health and Nutrition Examination Survey (NHANES); (2) applying the definition of disabling hearing loss used by the 2010 Global Burden of Disease Expert. Hearing Loss Team (hearing loss of 35 decibels or more in the better ear, the level at which adults could generally benefit from hearing aids). https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

4. Kochkin, S., & Rogin, C. M. A. (2000). Quantifying the obvious: The impact of hearing instruments on quality of life. Hearing Review, 7(1), 8–34.

5. Mulrow, C. D., Aguilar, C., Endicott, J. E., Velez, R., Tuley, M. R., Charlip, W. S., & Hill, J. A. (1990). Association between hearing impairment and the quality of life of elderly individuals. Journal of the American Geriatrics Society, 38(1), 45–50.

6. Lin, F. R., Metter, E. J., O'Brien, R. J., Resnick, S. M., Zonderman, A. B., & Ferrucci, L. (2011). Hearing loss and incident dementia. Archives of Neurology, 68, 214–220.

7. Global costs of unaddressed hearing loss and cost-effectiveness of interventions: a WHO report, 2017 ISBN 978-92-4-151204-6

Indication(s)

The Naída CI Sound Processors and Accessories are external components of the HiResolution™ Bionic Ear System, which is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss via electrical stimulation of the auditory nerve.

- **Adults**
  - Severe-to-profound bilateral sensorineural hearing loss or severe-to-profound unilateral hearing loss.

○ Postlingual onset of severe or profound hearing loss. ○ Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences). • **Children** ○ Severe-to-profound bilateral sensorineural deafness or severe-to-profound unilateral hearing loss. ○ Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea. ○ Little or no benefit from appropriately fitted hearing aids. In younger children (< 4 years of age), lack of benefit is defined as a failure to reach developmentally appropriate auditory milestones (such as spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or ≤20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL). In older children (≥ 4 years of age), lack of hearing aid benefit is defined as scoring ≤12% on a difficult open- set word recognition test (Phonetically Balanced-Kindergarten Test) or ≤30% on an open-set sentence test (Hearing In Noise Test for Children) administered using recorded materials in the soundfield (70 dB SPL).
Contraindications
• Deafness due to lesions of the acoustic nerve or central auditory pathway • Active external or middle ear infections • Cochlear ossification that prevents electrode insertion • Absence of cochlear development • Tympanic membrane perforations associated with recurrent middle ear infections
Precautions, Cautions & Warnings
CI-5280-xxx - Naída CI Q90 o This device should be used only by the individual for whom it is prescribed. o CHOKING HAZARD: contains small parts that pose a hazard of inhalation or choking. o Do not use a ComPilot if recipient has a pacemaker, as there is potential for interference. Contact a healthcare professional for more information. o Do not use or store the AB myPilot in shirt pockets if the recipient has a pacemaker, as there is potential for interference. Contact a healthcare professional for more information. o Ensure appropriate supervision when child is wearing the Naída CI sound processor and accessories. o Keep batteries and accessories out of children's reach as they may pose a choking hazard. o If any parts are swallowed consult a physician or hospital immediately. o Do not allow children to play with or leave them unattended with batteries. o Do not place batteries in your mouth. o Do not chew or swallow batteries. If this occurs, seek immediate medical attention. o Do not allow children to play with or operate the drying system unattended. o Using your sound processor and accessories contradictory to their intended use (e.g. mouthing, chewing) may cause bodily harm o Do not recharge disposable batteries. o Do not allow leaking battery fluid to come into contact with skin, mouth, or eyes. o Do not expose batteries to heat (e.g., do not store in direct sunlight or in a hot car). o Do not dispose of batteries in fire. o Do not allow children to charge batteries unattended.

	o Do not use any other power supply with the sound processor, AB myPilot remote control or ComPilot unless it is supplied by Advanced Bionics or Phonak. If needed call Advanced Bionics for a power supply replacement. o Do not use the AB myPilot or the ComPilot when they are plugged in to power sources such as wall outlets or other power sources that are USB compatible such as laptops. o The ComPilot comes with a neck loop antenna; do not touch the neck loop connectors at the same time. o Unplug the neck loop from the ComPilot before pairing your ComPilot to a Bluetooth device to avoid unexpected sounds. o Do not attempt to pair your ComPilot while driving or operating heavy machinery. o Do not stream music to your ComPilot while driving or operating heavy machinery. o Use your ComPilot for hands-free phone use only where permitted by law and only when you will not be distracted from the safe operation of your motor vehicle. o Power supplies and battery chargers should be operated in an open area to ensure adequate airflow. While no injury cases have resulted, components may become hot during normal use or a fault condition. If the device's temperature results in discomfort or pain when touched, disconnect the power source and contact your local Advanced Bionics representative. o Remove your sound processor and headpiece before entering a room where an MRI scanner is located. o Remove external equipment to stop stimulation if uncomfortable sounds are heard. o Having the correct magnet strength is important so that the recipient does not experience discomfort or retention issues. If an insufficient number of magnets is used in the headpiece, it may fall off more than is acceptable. If too many magnets are used in the headpiece, you may experience irritation or discomfort. Consult a clinician if there are any concerns regarding magnet strength. If deemed appropriate, an audiologist may insert additional magnets or remove magnets from the headpiece. Do not place additional magnets in the headpiece unless under the direction of a cochlear implant professional. If the recipient experiences any redness, irritation, or discomfort, discontinue use of the headpiece immediately and contact a cochlear implant center. See the headpiece "Instructions for Use" for additional information regarding adjustment of headpiece magnet strength. o If the sound processor or accessories become unusually hot, or warm, discontinue use immediately and contact Advanced Bionics or a clinician. o Store additional headpieces away from items with magnetic strips (e.g. credit cards, hotel room key cards), as this may de-magnetize cards. o Portable and mobile RF communications equipment, including radios and cellular phones, may affect sound quality of the Naída CI sound processor and accessories; however, there is no safety hazard associated with such equipment. o The Naída CI sound processor and accessories should be used in accordance with the electromagnetic compatibility (EMC) information provided in the 'Guidance and Manufacturer's Declaration' section of this Instructions for Use. o Only use the charger provided for charging AB PowerCel™ batteries. DO NOT use it to charge other batteries. Do not try to charge PowerCels* using a charger other than the one provided by Advanced Bionics. o Remove batteries from your sound processor when they are drained to prevent damage from possible leaking. o Do not expose any part of the Naída CI sound processor or accessories to extreme heat, such as an oven, microwave or hair dryer. o Do not use your AB myPilot or ComPilot accessories when instructed not to use wireless electronic devices, such as on airplanes.

	○ The AB myPilot should not come within 1 cm (1/2”) of the Naída CI processor while stimulating the implant, as doing so could cause the implant and sound processor to lose lock. If this happens, power down the processor and re-power on (done by disengaging the battery and reattaching). ○ When operating the device near a computer terminal or other strong electromagnetic fields, it may be necessary to be at least 60 cm (24”) away to ensure proper operation. If the Naída CI does not respond to the implant device because of an unusual field disturbance, move away from the disturbing field. ○ If the AB myPilot stops being able to transmit commands to the sound processor, it may be necessary to re-pair the AB myPilot with your sound processor. Consult the previous section of this user manual for instructions on re-pairing the AB myPilot. ○ If volume commands from your AB myPilot to your sound processor seem erratic, re-pair the AB myPilot and the Naída CI. ○ If the patient and/or caregiver is concerned about underlying skin conditions, have the attending physicians contact a dermatologist and/or rheumatologist. ○ For Pediatric or immobile patients, if there is any question of discomfort or changes to skin in the area of implant or at the location of the external devices, the caregiver must be bring it to the attention of the attending physician. **Additional precautions for Naida CI Q90 sound processor:** ○ StereoZoom, auto UltraZoom and UltraZoom will dampen sounds that are not in front of the recipient. ○ Do not use StereoZoom, auto UltraZoom or UltraZoom in an off-the-ear wearing configuration. ○ Use of WindBlock, EchoBlock and/or SoundRelax may affect the quality of sound. *PowerCels refer to both PowerCels and PowerCel Minis unless otherwise noted
CI-5850-xxx - Naída CI Q90 Acoustic Earhook	○ The device should be used only by the individual for whom it is prescribed. ○ CHOKING HAZARD: Acoustic Earhook contains small parts that could cause choking if swallowed. ○ If any parts are swallowed consult a physician or hospital immediately. ○ The Acoustic Earhook should only be used by the intended recipient and not by any other individual. ○ Do not allow children to play with or operate the drying system unattended. ○ Using your Acoustic Earhook contradictory to the intended use (i.e. mouthing, chewing) may cause bodily harm. ○ Remove your sound processor and headpiece before entering a room where an MRI scanner is located. ○ Remove Acoustic Earhook to stop stimulation if uncomfortably loud sounds are heard. ○ If the sound processor or accessories become unusually hot or warm, discontinue use immediately and contact your cochlear implant professional. ○ Do not expose the Acoustic Earhook to extreme heat, such as an oven, microwave or hair dryer. ○ Do not use the Acoustic Earhook unless the Wax Guard is properly seated and the appropriate dome is attached. ○ In the unlikely event that the dome gets stuck in the ear canal, it is strongly recommended to seek medical assistance to safely remove the part. ○ Exposure of the receiver to high humidity, sweat, or water could damage the receiver. ○ In the unlikely event that the Wax Guard becomes dislodged from the receiver while in the ear canal, contact your cochlear implant professional. Do NOT try to remove the Wax Guard from your ear canal yourself.
CI-5293-xxx (Naída CI M90)	• The device should be used only by the individual for whom it is prescribed. • CHOKING HAZARD: Contains small parts that pose a hazard of inhalation, choking, or ingestion. Using your sound processor and accessories contradictory to their intended use (e.g. mouthing, chewing)

CI-5295-xxx (Sky CI M90)	may cause bodily harm. If any parts are swallowed or inhaled, consult a physician or hospital immediately. • Ensure appropriate supervision when child is wearing the Marvel CI sound processors and accessories. Do not allow children to play with or leave them unattended with the sound processor or any of its accessories. • Power supplies and battery chargers should be operated in an open area to ensure adequate airflow. While no injury cases have resulted, components may become hot during normal use or a fault condition. If the device's temperature results in discomfort or pain when touched, disconnect the power source and contact your local Advanced Bionics representative. • Do not use any other power supply with the sound processor or accessories unless it is supplied by Advanced Bionics. If needed, please call Advanced Bionics for a power supply replacement. • Do not use accessories when they are plugged into power sources such as wall outlets, or other power sources that are USB compatible (e.g. laptops). • Do not allow leaking battery fluid to come into contact with skin, mouth, or eyes. • Do not expose batteries to heat (e.g., do not store in direct sunlight or in a hot car). • Remove batteries from your sound processor when they are drained to prevent damage from possible leaking. • Do not dispose of batteries in fire. • High levels of static electricity may damage electronic components of your sound processor or implant. Care should be taken to avoid exposure of the system to static electricity. • Do not attempt to pair your sound processor to any accessories while driving or operating heavy machinery. •Pair the sound processor to Bluetooth devices only in a secure environment. •Unwanted paired Bluetooth devices can be overwritten by pairing with authorized devices or can be deleted during fitting by your cochlear implant professional. • Do not stream audio to your sound processor while driving or operating heavy machinery. • Attenuating ambient sounds or adjusting environmental balance while streaming audio (either with the multifunction button or with the mobile application) may compromise situational awareness. • Use your sound processor for hands-free phone use only where permitted by law and only when you will not be distracted from the safe operation of your vehicle. • Do not use your Advanced Bionics wireless accessories when instructed not to use wireless electronic devices, such as on airplanes. • Remove your sound processor and headpiece before entering a room where an MRI scanner is located, and prior to having any surgeries that involve electrocautery and diathermy. • Remove your sound processor and consult your cochlear implant professional if uncomfortable sounds are heard or in case of discomfort, pain or skin irritation. • If the sound processor or accessories become unusually hot or warm, discontinue use immediately and contact Advanced Bionics or your cochlear implant professional. • The large Slim HP Color Cap is for use by recipients older than 3 years of age, as this color cap and the Slim HP magnet may become displaced upon dropping. • It is important to have the correct magnet strength, so you do not experience discomfort or retention issues. If magnet strength is insufficient, the headpiece may fall off more than is acceptable. If magnet strength is excessive, you may experience irritation or discomfort. Consult your cochlear implant professional if there are any concerns regarding magnet strength. If deemed appropriate, an audiologist may change the strength of the magnet in the headpiece. Do not change magnet strength unless under the direction of a cochlear implant professional. If you experience any redness, irritation, or discomfort, discontinue use of the headpiece immediately and contact a cochlear implant professional. See the headpiece instructions for use for additional information regarding adjustment of headpiece magnet strength. • Store additional headpieces away from items with magnetic strips (e.g., credit cards, hotel room keys, etc.) as they may de-magnetize cards. • The digitally-coded, inductive transmission technology used in this device is extremely reliable and experiences virtually no interference from other devices. It should be noted, however, that when operating the device near a computer terminal or other strong electromagnetic field (e.g. RFID system) , metal detectors, electromagnetic anti-theft systems), it may be necessary to be at least 24" (60 cm)

	away to ensure proper operation. If the Marvel CI sound processor does not respond to the implant device because of an unusual field disturbance, move away from the disturbing field. • The Marvel CI sound processors and accessories should be used in accordance with the electromagnetic compatibility information provided in the Guidance and Manufacturer's Declaration section of this document. • Although electromagnetic emissions of your Marvel CI sound processor have been confirmed within safe limits, some other devices could be sensitive to such emissions. If you notice other devices do not behave as expected when your sound processor is nearby, separate the devices. • Portable and mobile radio frequency (RF) communications equipment, including radios and cellular phones, may affect sound quality of the Marvel CI sound processor and accessories; however, there is no safety hazard associated with such equipment. • Do not expose any part of the Marvel CI sound processors or accessories to extreme heat, such as an oven, microwave, or hair dryer. • AutoSense OS 3.0 operating system, Speech in Loud Noise, Fixed Directional Mode, UltraZoom, UltraZoom + SNR Boost, and Speech in 360 programs may dampen sounds that are not in front of the recipient. • Use of WindBlock, EchoBlock, SoundRelax, NoiseBlock, and/or WhistleBlock may affect the quality of sound. • Do not use any programs other than an off-ear program when utilizing any off-ear wearing configuration (e.g., in a clip, in the M Waterproof Battery). • NOTE: In the United States, Fixed Directional mode, StereoZoom, UltraZoom, SoundRelax, NoiseBlock, WindBlock, and EchoBlock are approved for use in pediatric recipients 6 years and above who are 1) able to complete objective speech perception testing in order to determine speech performance and 2) able to report a preference for different coding strategies or features. • In the event that you experience any issues with your product, please contact your cochlear implant professional or the manufacturer. Do not attempt to service or modify the Marvel CI or its accessories. Doing so may compromise system performance and will void the manufacturer's warranty. Products should be serviced only at Advanced Bionics and damaged products should be returned to Advanced Bionics.
CI-5851-xxx (M Acoustic Earhook)	• This device should be used only by the individual for whom it is prescribed. • CHOKING HAZARD: Contains small parts that pose a hazard of inhalation, choking, or ingestion. If any parts are swallowed or inhaled, consult a physician or hospital immediately. • Do not leave children unattended with or allow children to play with the M Acoustic Earhook. • Do not allow children to place the M Acoustic Earhook in the mouth. • The M Acoustic Earhook should only be used by the intended recipient and not by any other individual. • Exposure of the M Acoustic Earhook to high humidity, sweat, or water could damage the speaker unit. • Placing the M Acoustic Earhook within close proximity to the headpiece magnet may damage the M Acoustic Earhook. • Remove your sound processor and consult your cochlear implant professional if uncomfortable sounds are heard or in case of discomfort, pain or skin irritation. • Do not use the M Acoustic Earhook unless the earwax protection is properly seated and the appropriate dome is attached. • In the unlikely event that the dome or earwax protection becomes dislodged in the ear canal, contact your cochlear implant professional. Do not try to remove the dome or earwax protection from your ear canal yourself. • If you observe any changes in sound quality with the M Acoustic Earhook, please contact Advanced Bionics or your cochlear implant professional. In the event that you experience any issues with your product, please contact your cochlear implant professional or the manufacturer. Do not attempt to service or modify the Naída CI or its accessories. Doing so may compromise system performance and will void the manufacturer's warranty. Products should be serviced only at Advanced Bionics and damaged products should be returned to Advanced Bionics.

Possible Adverse Events

CI-5280 (Naída CI Q90 Sound Processors)

Undesirable side effects of Naída CI system may include skin irritation and discomfort from pressure on the ear, device overheating, or overly loud sounds. If any undesirable side effect is encountered, please remove your sound processor and consult your cochlear implant professional.

CI-5850 (Naída CI Q90 Acoustic Earhook)

Undesirable side effects of Naída CI system may include skin irritation and discomfort from pressure on the ear, device overheating, or overly loud sounds

CI-5293-xxx (Naída CI M90), CI-5295-xxx (Sky CI M90), CI-5851-xxx (M Acoustic Earhook)

Undesirable side effects of your Marvel CI sound processor and accessories may include skin irritation and discomfort from pressure on the ear, device overheating, or overly loud sounds. If any undesirable side effect is encountered, please remove your sound processor and consult your cochlear implant professional.

Claimed clinical benefit

The intended clinical benefit of the Naída CI Sound Processor and Accessories as part of the HiRes™ Bionic Ear System is defined as:

- For adults:
  - Word recognition score in quiet higher or equal to 30% at a minimum of 12 months follow-up OR improvement higher than 30% compared to pre-operative stage

  AND/OR
  - Sentence recognition score in quiet higher or equal to 40% at a minimum of 12 months follow-up OR improvement higher than 40% compared to pre-operative stage
- For children:
  - Before 4 years old: auditory awareness higher than 50% at a minimum of 12 months follow-up
  - Above 4 years old: word/sentence recognition in quiet higher than 30% or improvement of 30% at a minimum of 12 months follow-up.

Expected lifetime

CI-5280-xxx-Naída CI Q90	5 years
CI-5850-xxx - Naída CI Q90 Acoustic Earhook	1 year
CI-5293-xxx (Naída CI M90) CI-5295-xxx (Sky CI M90)	5 years
CI-5851-xxx (M Acoustic Earhook)	1 year

Invasiveness

Non-invasive (external)

Contact duration

Intact skin, >30 days

Type of use

Single-use*
Sterile
Non-sterile
Novel product
☐ YES x NO
Novel related clinical procedure
☐ YES x NO
Explanation of any novel features
N/A

*Single use as they do not fit the MDR (nor FDA) reprocessing definition of reusable devices. These devices are used on one individual during a single procedure corresponding to the lifetime of the devices.

4.5 Principle of Operation

The HiRes™ Bionic Ear System is a cochlear implant system designed to provide useful hearing to individuals with severe-to-profound hearing loss. It consists of internal and external components. Figure 4 illustrates the connections between CI components, including the fitting software. The cochlear implant (internal component), CPI fitting interface and fitting software are not under investigation but are included for completeness.

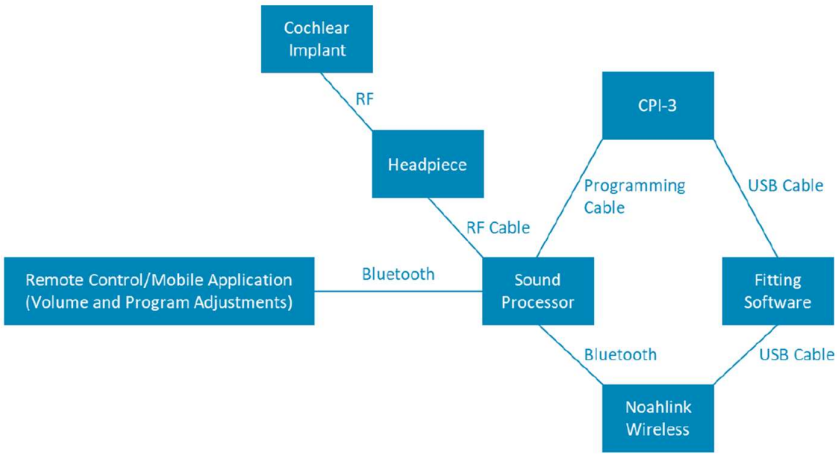

Figure 4 : Diagram of the connections between CI components

Figure 5 illustrates the auditory pathway with the cochlear implant and the behind-the ear sound processor. Sound is captured by microphones. Note: Advanced Bionics cochlear implants can receive sound from T-Mic, headpiece and processor microphones and auxiliary audio inputs sources.

1. The sound processor converts the captured sound into detailed digital information.

2. The processor sends power and digital information via the headpiece to the implant which is implanted under the skin.

3. The implant converts the digital information from the processor into electrical stimulation which is delivered to the auditory nerve through the electrode array. The auditory (hearing) nerve sends impulses to the brain where they are interpreted as sound.

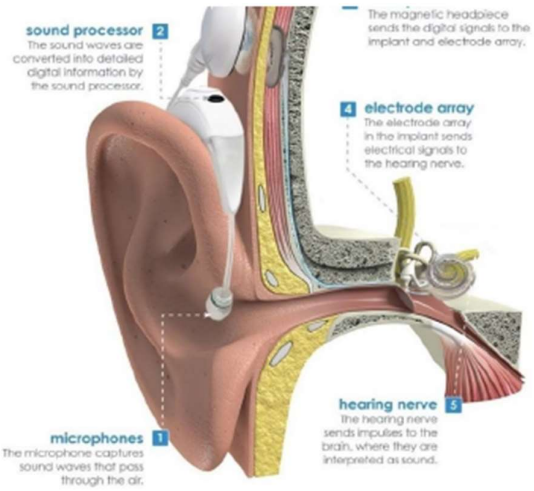

Figure 5 : Auditory pathway of cochlear implant and BTE

4.6 Origin of development

The development of sound processor is based on addition and incrementation of new features to existing technologies. The Marvel sound processor is based on a previous generation of processor called Naída CI Q which is itself an improvement on the processor generation called Harmony. Electro-acoustic stimulation (EAS) was introduced with the Acoustic Earhook with the Naída CI Q sound processor.

4.7 Materials in contact with tissues

For each device under investigation, the materials in contact with tissues are listed in tables below (Table 5, Table 6, Table 7 and Table 8). Biocompatibility reports for each device and materials are available upon request.

Table 5 : Naída™ CI Q90 material specifications

Description	Raw Material	Colorants	Direct contact contact with human body
Case Top			Skin
Case Bottom			Skin
Program Button			Skin
Volume Rocker			Skin

Description	Raw Material	Colorants	Direct contact contact with human body
	[redacted]	[redacted]	
Light Pipe			Skin
Acoustic Vent Mesh			Skin
Acoustic Vent Overmold			Skin
PIN 0.7 x 8.9mm			Skin
Earhook Locking Pin			Skin
PIN 0.7 x 6.7mm			No
P2i Coating (external)			Skin
Headpiece Connector			Skin
BTE Connector: Housing			Skin
BTE Connector: Detent Spring			Skin
Frame			No
PIN 0.7 x 7.15mm			No
PIN 0.7 x 5.4mm			No
Microphone Suspension (F)			No
Microphone Suspension (R)			No
Seal			No

Table 6 : Naída CI Q90 Acoustic Earhook material specifications

Description	Raw Material	Colorants	Direct contact or indirect contact with human body
Wire Jacket	[redacted]	[redacted]	Skin
Nozzle			Skin
Retention			Skin
Connector Body			Skin
Connector Socket			Skin
Housing Receiver			Skin
Housing Receiver Ink			Skin
Housing Receiver Ink			Skin
Housing Receiver Ink			Skin
Receiver			No
Receiver Cover Front			Skin
Receiver Cover Back			Skin
Epoxy Adhesive			Skin
CeruStop			Skin
Pin Removal Tool Body			Skin

Description	Raw Material	Colorants	Direct contact or indirect contact with human body
Pin Removal Tool Pin	[redacted]		Skin

Table 7 : Marvel CI sound processors material specifications

Description	Raw Material	Color	Direct contact contact with human body
Case Top, Case Bottom, Volume rocker	[redacted]		Yes, skin
Light Pipe			Yes, skin
Frame			No
Plate T-Mic Pins			No
Contact Pin			No
Suspension Microphone			No
Housing Connector BTE, Plate Locator BTE Connector			Yes
Battery Contact			No
Detent Spring			Yes, skin
Mic Retention Frame			No
Microphone cover			No
Mic Seal			No
Connector Seal			No
T-Coil Compression Suspension			No
Pin			No
Locking Pin			Yes, skin
P2i Coating (external)			Yes, skin

Table 8 : M Acoustic Earhook material and specifications

Description	Raw Material	Color	Direct contact contact with human body
Nozzle	[redacted]		Yes, skin
Connector			Yes, skin
Inner Mold			No
Wire Jacket			Yes, skin
Cover Back, Cover Front			Yes, skin
Retention			Yes, skin
O-Ring			Yes, skin
Housing Receiver			Yes, skin
Housing Receiver Ink			Yes, skin

4.8 Description traceability

This project includes retrospective analyses of clinical data. All devices were used in the clinical routine and tracked according to the appropriate regulations.

4.9 Summary of the necessary training

Personnel involved at the center are required to be familiar with the center's patient database and conventions for data coding and be able to extract data from it as well as compare data within it to e.g. ensure compliance with the inclusion criteria. Besides being familiar with this plan, no specific training is required.

5.0 Study Design and Justification

5.1 Description and justification for the design of the clinical investigation

This monocentric observational post-market clinical follow-up study (PMCF) of cochlear implants with Electro-Acoustic Stimulation is based on a retrospective data analysis of anonymized clinical data, in order to minimize risk and effort for the subjects. Reliable data to evaluate the efficacy of the Naída CI Q sound processor and the Naída CI M sound processor and their associated acoustic earhook, are already available in the form of data collected within the clinical routine. Analyses of these data do not have an influence on clinical routine and therefore do not impose any additional effort from the subjects.
A retrospective analysis of clinical data also minimizes the amount of data collected on each subject and consequently minimizes the risk of loss of personal data. To further protect subjects' data privacy, only anonymized data will be provided to AB.

5.2 Evaluation of the results of the relevant pre-clinical testing and prior clinical investigations

The Naída CI Q sound processor and the Naída CI M sound processor and associated acoustic earhook were qualified for long-term use in/on the human body through extensive preclinical testing using industry standards and specialized testing targeted for cochlear implants. This testing considered anticipated use case stresses which could affect the stability and reliability of the device, such as: impact, flexure and tensile stresses; body fluid/tissue contact; anticipated medical procedures for the patient and environmental elements.

The stability of the AB implants is assured by the materials and processes used in the manufacture of the devices. Reliable data to evaluate the efficacy of the HiRes Ultra Cl HiFocus SlimJ implant and Naída CI Q sound processor and the Naída CI M sound processor and associated acoustic earhook are available in the form of data collected within the clinical routine. These data reflect real world evidence and are therefore suitable for PMCF objectives. Analyses of these data do not have an influence on clinical routine and do therefore not impose any additional effort on the subject.

5.3 Evaluation of relevant clinical data

The post market surveillance data including reliability, complaint, adverse events and Corrective Action Preventive Action (CAPA) data ensure that safety is consistently monitored. Once identified the events are thoroughly investigated, analyzed for root causes and the necessary actions taken to mitigate any risks.

The literature reviews performed examined all aspects of cochlear implantation clinical outcomes. These were conducted according to the state-of-the-art methodology and identified a large amount of published literature. The benefits underline the substantial benefits of cochlear implantation when applied to selected candidates having severe to profound sensorineural hearing loss.
These considerations indicate that the devices under evaluation have a positive risk/benefit profile and hence are suitable for clinical application. The data available from the risk analysis, the literature reviews, standards compliance, and data on long-term reliability all indicate that the products perform well in comparison to other cochlear implants and accessories that are already on the market.

5.4 Description of the clinical development stage

Not applicable, all devices under investigation are CE-marked.

5.5 Description of the measures taken to minimize or avoid bias, including randomization and blinding/masking

The cohort shall reflect the general population and represent real world data. The subjects are not selected, fulfillment of all inclusion criteria is the one condition. Factors such as gender or lifestyle are not expected to have an effect on study outcomes. By selecting all eligible subjects from the clinic's database in the analysis, selection bias is minimized.

5.6 Description of the specific medical or surgical procedures

There are no specific medical or surgical procedures included in this analysis. Cochlear implantation and follow-up of the subjects were performed according to the center's clinical routine.

5.7 Number of investigational devices

As this is a retrospective and observational clinical study, the number of devices under investigation corresponds to the number of included subjects. Bilateral patients received two devices. Therefore, the number of subjects is potentially lower than the number of devices.
This study will include all patients fulfilling inclusion and exclusion criteria and registered in the clinical patient database at the time of data extraction.

5.8 Description of the exposure to the investigational device

Investigational devices are CE marked and used according to their intended purpose as described in the IFU. Please, refer to section 4 for the description of the devices.

5.9 List of any other medical device or medication to be used during the clinical investigation

As this device is part of a system, the other medical devices used are the components of the cochlear implant, i.e., the compatible implant (HiRes Ultra and HiRes Ultra 3D with the SlimJ electrode in this study), headpieces and other accessories (connection cables, batteries) which are described above.

There is no additional medical device or medication involved as part of the study procedure.

5.10 Definition of completion of the clinical investigation

Not applicable, this a retrospective observational PMCF study for which data are already collected. This investigation will be considered completed when the report is finalized and all regulatory requirements are fulfilled, as applicable.

6.0 Objectives

6.1 Primary Efficacy Objective

The primary efficacy objective is to demonstrate that the group mean monosyllabic word recognition score with the EAS system in quiet at twelve months after first fitting is 30% or better. This efficacy outcome has been defined in accordance with the State-Of-The-Art (SOTA) performed by AB, and claimed clinical benefits for the HiRes Bionic Ear System from AB.

6.2 Secondary Efficacy Objective

The secondary efficacy objective is to demonstrate that the group mean sentence recognition score with the EAS system in quiet at twelve months after first fitting is 40% or better.
Subsidiary objectives include:

- Observation of the evolution of the mean monosyllabic word recognition score with the EAS system in quiet at 6, 12 months, 2, 3, 4 and 5 years after first fitting and more if available
- Observation of the evolution of the mean sentence recognition score with the EAS system in quiet at 6, 12 months, 2, 3, 4 and 5 years after first fitting and more if available
- Observation of the evolution of the mean sentence recognition score with the EAS system in noise at 6, 12 months, 2, 3, 4 and 5 years after first fitting and more if available.

There are no safety objectives for this clinical investigation. Safety events will not be collected retrospectively for the included subjects.

7.0 Study Protocol

7.1 Subject Population and Selection Criteria

7.1.1 Number of subjects

As a retrospective analysis, this study will include all patients fulfilling inclusion and exclusion criteria and registered in the clinical patient database at the time of the extraction of the data.
Considering the EAS population already implanted at MHH since January 2017 (estimated at 50 users) and based on the estimation of patients who provided informed consent and who fulfill the inclusion criteria, the size of the included population is estimated to be around 30 to 40 subjects.
Any CI recipient from the implicated center (MHH in Hanover, Germany) implanted with an Ultra or an Ultra 3D implant and meeting the below defined inclusion criteria will be included.

7.1.2 Description of procedures for the selection of subject

This analysis only includes observational retrospective analyses of clinical data. Data related to all eligible subjects will be queried from the clinical patient database.

7.1.3 Inclusion Criteria

- Being implanted with Ultra or Ultra 3D SlimJ
- Being a user of the "acoustic earhook" system
- Having provided informed consent regarding use of his/her data for research.

7.1.4 Exclusion criteria

There are no specific exclusion (and non-inclusion) criteria, all patients fulfilling inclusion criteria described above and registered in the clinic patient database will be included.
The absence of exclusion criteria is based on the intention to have an exhaustive approach. By eliminating all restrictions, it is expected to include a representative range of participants, thereby maximizing the generalizability of the results to the general population.

7.1.5 Anticipated distribution of enrolment and period of enrolment

This section is not applicable, this is a retrospective observational study for which data are already collected. Patients implanted between January 2017 and August 2022 and fulfilling above selection criteria will be included.
Only one expert center will be part of this study. The center enrolled all patients.

7.1.6 Point of randomization

There is no randomization as this is a retrospective observational study on data collected during clinical routine.

7.1.7 Expected duration of each subject participation

This section is not applicable. This is a retrospective observational study on data already collected with no further subject participation required. Subjects with follow-up up to 5 years after first fitting of the Naída CI Q or Naída CI M sound processors and associated earhooks can be included.

7.1.8 Total expected duration of the study

This is a retrospective observational study on data already collected. The duration of the investigation corresponds to the time needed to analyze the data, prepare the report, and fulfill any regulatory requirement, as applicable. A total of 3 months is estimated to analyze the data and prepare the report.

7.2 Study Endpoints

7.2.1 Primary Efficacy endpoint

The primary efficacy endpoint is the group mean Freiburger Monosyllabic Word score (in quiet) of 30% or more at twelve months after the first fitting.

7.2.2 Secondary Efficacy endpoint

The secondary efficacy endpoint is the group mean HSM score (in quiet) of 40% or more at twelve months after the first fitting.
Subsidiary efficacy endpoints include:

- The mean monosyllabic word recognition score with the EAS system in quiet at 6, 12 months, 2, 3, 4 and 5 years after the first fitting
- The mean sentence recognition score with the EAS system in quiet at 6, 12 months, 2, 3, 4 and 5 years after the first fitting
- The mean sentence recognition score with the EAS system in noise at 6, 12 months, 2, 3, 4 and 5 years after the first fitting.

Regarding the sentence recognition score, either HSM sentence test or the OlSa recognition score were collected during the clinical routine. The center initially collected the HSM sentence test routinely and then switched to the OlSa recognition score. Therefore, throughout follow-up the speech test used to evaluate performance may have changed. Regarding the secondary objective and associated endpoint, the HSM sentence test will be used.

7.2.3 Safety Endpoint

This investigation focuses only on performance aspects. This retrospective data analysis is conducted for PMCF purpose as required following clinical evaluation of the device. The need for additional performance data specific to EAS user was identified.

7.3 Study Procedures

7.3.1 Description of all the clinical investigation related procedures for the subjects

As a retrospective analysis, this study does not include any investigational procedure outside of the clinical routine for the included patients.

7.3.2 Measurements procedures

The original publications describing the tests carried out are presented in the appendices (*Hahlbrock, 1953*, *Hochmair-Desoyer et al., 1997* and *Wagener et al. 1999*).
Publications demonstrating the accuracy of the Freiburger Monosyllabic Word, Hochmair-Schulz-Moser and Oldenburger Sentence tests for evaluating speech understanding applied to the German language are listed in the bibliography section. Please note that these publications are in German.

- Freiburger Monosyllabic Word Test
  The Freiburger Monosyllabic Word Test was conducted with a clinical audiometer. The signal was presented at 65dB from a loudspeaker in front of the subject. The loudspeaker presenting the material was placed one meter in front of the CI recipient. The score was obtained as the percentage of words correctly understood.
  Conditions: at baseline the monosyllabic word test was conducted in free field on the ear to be implanted. The patient used the hearing aid setting with which he/she obtained best results. The score obtained was the baseline monosyllabic word score. With the CI system the monosyllabic word test was measured in free field using the processor in its normally used setting.

- Hochmair-Schulz-Moser Sentence Test
  The Hochmair-Schulz-Moser (HSM) Sentence Test was conducted with a clinical audiometer. The signal was presented at 65dB from a loudspeaker in front of the subject. The loudspeaker presenting the material was placed one meter in front of the CI recipient. The score was obtained as the percentage of words correctly understood.
  For speech intelligibility in noise a speech-shaped noise was presented additionally at 55dB SPL (SNR of +10dB).
  Conditions: at baseline the HSM test was conducted in free field on the ear to be implanted. The patient used the hearing aid setting with which he/she obtained best results. With the CI system the HSM test was measured in free field using the processor in its normally used setting.

- Oldenburger Sentence Test (OlSa)
  The Oldenburger Sentence Test was performed in an adaptive way using a clinical audiometer. Both, signal and noise, were presented from the loudspeaker in front of the subject. The noise was presented at 65dB in a continuous way. The signal was varied to obtain the signal-to-noise ratio at which the patient correctly understood 50% of the words. This is called Speech Reception Threshold (SRT) measured in dB.
  Conditions: at baseline the Olsa was conducted in free field on the ear to be implanted. The patient used the hearing aid setting with which he/she obtained best results. The SRT obtained in this condition was the baseline SRT. With the CI system the OlSa was measured in free field using the processor in its normally used setting.

7.3.3 Methods and timing for assessing, recording and analyzing variables

The data collected for this retrospective observational study were already collected by the expert center as part of the clinical routine management of patients. Analysis to be performed for this investigation is described in section 8.2.

7.3.4 Equipment to be used for assessing the clinical investigation variables

To obtain speech perception scores and in the Freiburger monosyllabic word test, the HSM sentence test and speech reception threshold in the Oldenburger sentence test, the clinics used a standard audiometer where the respective tests are implemented.

7.3.5 Description of those activities performed by Sponsor representatives

The anonymized data will be analyzed by the Sponsor and a report will be provided to the investigator. The Sponsor is responsible for any regulatory requirements, as applicable.

7.3.6 Any known or foreseeable factors that may compromise the outcome of the clinical investigation or the interpretation of results

The study carried out is a monocentric study, which may constitute a bias: the population may not reflect the overall population using the acoustic earhook. Additionally, only anonymized data will be provided to AB, preventing the possibility to verify source data. Therefore, no monitoring will be performed for this investigation.

7.3.7 Methods for addressing these factors in the clinical investigation

There are no methods for addressing the potential bias due to the study being monocentric within the clinical investigation, except performing additional clinical investigations in other centers.
In order to ensure the validity of the transmitted data, a contract will be drawn up between the centre and AB with the aim of defining roles and responsibilities. The center will be responsible for the verification of the validity of the data.

7.3.8 Specific subject's follow-up after termination of the study

Not applicable, this a retrospective observational study for which the data were already collected in the context of the clinical routine care.

7.4 Study Visits and Visit Windows

All data analyzed will be collected retrospectively from the clinical database, no dedicated visits are necessary for this protocol. The scheduled routine of patient care visits is presented in the **Error! Reference source not found.**.

Table 9 : Schedule of clinical routine patient care visits at MHH

Procedures	Pre-Op	Surgery	First Fitting	Follow-up fitting (3 and 6 Mo)	Yearly Appointment (1 year, 2, 3, 4, 5… years)
Counselling, selection of implant manufacturer	X				
Pure tone audiometry	X		X	X	X
Implantation of cochlear implant		X			
Implant check		X	X	X	X
Imaging		X			
Rehabilitation training			X		
Medical check	X		X		X
Speech perception test	X		X	X	X
Finetuning of fitting			X	X	X

7.5 Withdrawal of Subjects

This section is not applicable to a retrospective data analysis. However, a subject's data may be withdrawn from the analysis if it is subsequently discovered that the inclusion of a subject does not comply with the selection criteria.

8.0 Statistics

8.1 Sample Size Justification

This analysis only includes retrospective clinical data. All data from subjects fulfilling the inclusion criteria will be included.

8.2 Statistical Design & Data Analysis

8.2.1 Analytical procedures

Data will be analyzed using descriptive statistics and further analyses might be performed using applicable parametric or nonparametric methods, depending on the number of available datasets.

The study plans to screen up to 50 patients. Among these 50 potential subjects, based on the estimation of patients who provided informed consent and who fulfill the inclusion criteria, the size of the included population is estimated to be around 30 to 40 subjects.

8.2.2 Primary efficacy hypothesis

The primary efficacy hypothesis is based on the total number of subjects n and score (percentage of words correctly understood) in the Freiburger Monosyllabic Word Test twelve months after the first fitting.

Thus, the primary efficacy hypothesis is:

$$\frac{\sum(Word\ Score\ 12\ months)}{N} > 30\%$$

With:

Word Score 12 months = % of words correctly recognized at 12 months after the first fitting

N = number of datasets

8.2.3 Secondary efficacy hypothesis

The second efficacy hypothesis is based on the total number of subjects n and score (percentage of words correctly understood) in the HSM sentence test in quiet and in noise one year post activation.
Thus, the secondary efficacy hypothesis is:

$$\frac{\sum(HSM\ Score\ 12\ months)}{N} > 40\%$$

With:
HSM Score 12 months = % of correct sentence recognized at 12 months in quiet and in noise after the first fitting
N = number of datasets

- **Pass/fail criteria to be applied to the results of the clinical investigation**

The primary efficacy hypothesis needs to be fulfilled in order to consider this investigation successful.

- **Procedure for reporting any deviation(s) from the original statistical plan**

In case of a deviation from the statistical plan, the final report will highlight and justify the deviations.

- **Minimum and maximum number of subjects to be included for each center in multicenter clinical investigations**

This section is not applicable. The study is a monocentric study.

9.0 Adverse Events and Device Deficiencies

An Adverse Event (AE) is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. This definition includes events related to the investigational medical device or the comparator. This definition includes events related to the procedures involved. For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparator.
A Serious Adverse Event (SAE) is an adverse event that led to any of the following:
a) death
b) serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:

1) life-threatening illness or injury, or

2) permanent impairment of a body structure or a body function including chronic diseases, or

3) in-patient or prolonged hospitalization, or

4) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function,

c) foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment.

Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

Adverse event and device deficiencies will not be collected during this investigation.

This retrospective data analysis is conducted for PMCF purpose as required following the devices clinical evaluation. The need for additional performance data specific to EAS user was identified.

The clinical evaluation of device under investigation concludes that devices under investigation are safe:

"*All risks from the risk analysis are minimized, acceptable when balanced with benefits, and consistent with a high level of health and safety protection. All risk mitigations related to the clinical evaluation are sufficient since no new risk nor emergent risk have been identified. Limited safety issues related to the use of the Naida CI sound processors and accessories were reported in the included clinical datasets. These safety issues are consistent with those retrieved from literature, including State-of-the-Art, and those observed in PMCF activities.*

Safety issues related to external CI components are rare and within an acceptable rate as observed in the Clinical Evaluation Report (<5%). The majority of CI-related safety issues stem from the implantation surgery or the internal device."

Therefore, this investigation focuses only on performance aspects and no safety data will be collected.

10.0 Informed Consent Process

When patients are being treated, the expert center informs them that their medical data can be used for any research purposes. Patients either accept or refuse. Therefore, only data for which subjects have given their consent may be collected as part of the clinical investigation. There will be no specific inform consent for this clinical investigation.

11.0 Vulnerable Population

In this analysis, there is no restriction of age in the inclusion criteria. Children below the age of 18 years are considered as vulnerable subjects. Considering the retrospective observational design of this investigation, there is no additional nor specific risk that might be encountered in this vulnerable population. Enrollment of children is justified in order to collect data reflecting the pediatric population.

The cochlear implant works in the same way whatever the person's age, gender and her status (pregnant women, breast-feeding women, etc.). Cochlear implantation does not change the way

people are cared for regarding any other condition. The addition of cochlear implants in these populations has already been carried out, as this is a retrospective observational study.

12.0 Benefits and Risks

12.1 Risks associated with participation in the clinical investigation

As explained in section 5, a retrospective observational study design with anonymization of clinical data was chosen for this analysis to minimize risk and effort for subjects.
Analyses of the data do not have an influence on clinical routine and therefore do not impose any additional risk on the subject. Therefore, there are no specific risks related to the participation to this study.

12.2 Anticipated clinical benefits

The benefits will be the same for both Naída CI Q and Naída CI M sound processor recipients considering that the Acoustic Earhook for both sound processor are the same. The benefit of the study is the combined electrical and acoustic stimulation, which restores hearing in both silence and noise resulting in overall and hearing-specific improvement of quality of life.

The Intended Clinical Benefit of the sound processors and acoustic earhook as part of the HiResolution Bionic Ear System is to provide combined electrical and acoustic stimulation to restore hearing in silence and in noise when sound processors are enabled with the Acoustic Earhook.
The clinical benefits can be measured as follows:
For adults

- Word recognition score in quiet higher than or equal to 30% at a minimum of 12 months follow-up OR improvement higher than 30% compared to pre-operative stage.

AND/OR

- Sentence recognition score in quiet higher than or equal to 40% at a minimum of 12 months follow-up OR improvement higher than 40% compared to pre-operative stage.

For children:
Before 4 years old: auditory awareness higher than 50% at a minimum of 12 months follow-up.
Above 4 years old: word/sentence recognition in quiet higher than 30% or improvement of 30% at a minimum of 12 months follow-up.

12.3 Anticipated adverse device effects, residuals risks and possible interactions with concomitant medical treatments

The risks are similar for the two sound processors and associated acoustic earhooks under investigation. There are no specific risks related to the participation to this investigation as this is a retrospective observational data analysis in which data are already collected according to the center clinical care routine.
Residual risks and potential side-effects are listed in Table 4.

Users of the Naída CI Q & Naída CI M sound processors and associated acoustic earhook in the European Union should report any serious incident to their local competent authority and to Advanced Bionics.

12.4 Benefit-risk ratio

This retrospective observational study does not impose any additional risk on the patients or their data, as there are no additional procedures. According to the risk analysis, risks are mitigated by design, inspections and tests of each specific implant and training. All risks have been reduced to the greatest extent possible and is available on request. The overall residual risk remains acceptable when weighed against the benefit of providing sound and speech perception to patients with severe to profound sensorineural hearing loss. This retrospective observational study does not impose any additional risk on the patients or their data.

13.0 Suspension or Premature Termination

Not applicable, this is a single-center observational study is based on a retrospective analysis of anonymized clinical data with no additional procedures. Data are already collected and only analysis of the data, and writing of the report are necessary.

14.0 Monitoring, Device Accountability and Data Management

14.1 Monitoring Procedures

As this study is a retrospective observational study with anonymized clinical data on a CE-marked device without additional procedures for the subjects, the monitoring of this study is included in the conventional monitoring of patients during routine care by the hospital center.
Only anonymized data will be provided to AB, preventing the possibility to verify source data. Therefore, no monitoring will be performed for this investigation.
In order to ensure the validity of the transmitted data, a contract will be drawn up between the centre and AB with the aim of defining roles and responsibilities. The center will be responsible for the verification of the validity of the data.

14.2 Device Accountability

This is a retrospective observational study on data already collected. The devices under investigation are CE-marked and available on the market and were provided to the patient through standard distribution channels. Therefore, there is no device accountability in this study.

14.3 Data Management Procedures / Case Report Forms

As this is a retrospective observational study, the data were collected from the center database (MHH in Hanover, Germany), therefore, there are no Case Report Forms (CRF). Data source documents are the medical files of the patients, as filled in the center database.

The MHH will provide anonymized clinical data in the form of a spreadsheet including speech performance tests data and demographic data.

Details of the data collected are presented in the following list.

- Consent
- Demographics:
    - Native language
    - Age at implantation
    - Gender
    - Etiology
    - Implant (type, date, side)
    - Hearing aid (start right, end right, start left, end left)
    - Hearing impairment (right, left)
- Speech performance:
    - Freiburger Monosyllables (quiet) at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after first fitting with the acoustic earhook as available
    - HSM and/or OIsa (quiet) at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after first fitting with the acoustic earhook as available
    - HSM in noise (55dB SPL (SNR of +10dB)) and/or OIsa in noise (50% SRT with a 65dB noise signal) at 6 months, 1 year, 2 years, 3 years, 4 years and 5 years after first fitting with the acoustic earhook as available

14.4 Procedures used for data review, database cleaning, and issuing and resolving data queries

Retrospective anonymized data exported from the clinical patient database will be made available to AB in a spreadsheet format. The investigator ensures data integrity as providing anonymized data does not allow for data monitoring on behalf of AB.

14.5 Procedures for verification, validation and securing of electronic clinical data system (if applicable)

This section does not apply, as no data collection form (CRF) is used.

14.6 Procedures to maintain and protect subject privacy

There are no specific procedures required to maintain and protect the confidentiality of subjects as the data collected are anonymized clinical data.

14.7 Procedures for data retention

Only retrospective data analyses of clinical data are included in this investigation. For the clinical data from the center, retention procedures from the hospital apply. Data will be presented and analyzed in a report as well as in the Post-Market Clinical Follow-up report.

14.8 Specified retention period

There is no specific retention period for the data collected in this study. Once the report is finalized, the spreadsheet data provided by the center will be deleted.

14.9 Other aspects of clinical quality assurance, as appropriate

The investigator will assure proper implementation and conduct of the data selection, compilation and anonymization.

15.0 Statements of Compliance

This clinical investigation is conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki.

This clinical investigation is conducted in compliance with ISO 14155:2020, the European Medical Device Regulation (MDR EU 2017/745) and the German Medical Device law (Medizinprodukterecht-Durchführungsgesetz-MPDG). However, as far as only anonymized data will be provided to AB, preventing the possibility to verify source data, no monitoring will be performed for this investigation.
Moreover, in compliance with MHH ethics committee requirements, ethical approval is not mandatory in the case of a retrospective data analysis of anonymized data.
Since all devices are market approved and used according to the approved indication there is no study specific insurance required according to any regional or local regulation.

16.0 Amendments and Deviations

16.1 Description of the procedures to amend the CIP

The protocol must be followed exactly. Any changes to the protocol must be implemented through a formal protocol amendment. An amendment cannot be initiated until it has been approved in writing by the Sponsor, the Investigator, and the EC, as applicable. Administrative changes that do not affect the subject risk ratio may be made after consulting AB AG.

16.2 Deviations

The investigator must agree that the study will be conducted according to this CIP, the principles of the Declaration of Helsinki, the standard ISO 14155:2020, and local regulations, as applicable.

Any deviation that affects the scientific soundness of the study or any aspect of the subject's safety, rights or wellbeing may be a cause to close the study at the investigational center. In addition, these deviations will require urgent reporting to EC, as applicable.

Amendments and deviations from this protocol will be discussed in the study report.

17.0 Publication Policy

No publication of the results from this study is planned.

18.0 Bibliography

Hey et al., 2014, Investigation of a matrix sentence test in noise: Reproducibility and discrimination function in cochlear implant patients, International Journal of Audiology, 53:12, 895-902, DOI: 10.3109/14992027.2014.938368

Winkler et al., 2016, Test-Retest-Reliabilität des Freiburger Einsilbertests [Test-retest reliability of the Freiburg monosyllabic speech test]. HNO. Aug;64(8):564-71. German. DOI: 10.1007/s00106-016-0166-2.

Kollmeier et al., 2015. The multilingual matrix test: Principles, applications, and comparison across languages: A review. Int J Audiol. ;54 Suppl 2:3-16. DOI: 10.3109/14992027.2015.1020971.

19.0 Study Sites, Investigators and External Organizations

19.1 Study Sites and Investigators

19.2 External Organizations

Not applicable

20.0 Revision History (if applicable)

This is the first version of the CIP.

CIP Sponsor Signature Page

[redacted] Research Audiologist, Advanced Bionics, Hannover

Date: 1/21/2024 Signature: DocuSigned by: [redacted]

[redacted] Regulatory Affairs Manager, Advanced Bionics, Valencia

Date: 1/19/2024 Signature: DocuSigned by: [redacted]

[redacted] Senior Director Clinical Research, Advanced Bionics, Hannover

Date: 1/19/2024 Signature: DocuSigned by: [redacted]

[redacted] Global VP Research & Technology and Clinical Affairs, Advanced Bionics, Hannover

Date: 1/19/2024 Signature: DocuSigned by: [redacted]

[redacted] Head of Finance/Controlling for AB International & MD AB AG Switzerland, Stafa:

Date: 1/19/2024 Signature: DocuSigned by: [redacted]

CIP Investigator Signature Page

I, the undersigned, have read and understand the protocol specified above and agree on its content. I agree to perform and conduct the study as described in the protocol and in accordance with the relevant parts of the ICH Guidelines for GCP, ISO 14155:2020, and MDR (EU) 2017/745, the Declaration of Helsinki, and the pertinent individual country laws/regulations applicable in Germany.
In addition, I assume responsibility for protocol compliance for persons to whom I delegate study related tasks.

Prof. Andreas Büchner, Scientific Director,
Medizinische Hochschule Hannover, Hannover

Date: 1/22/2024 Signature: [redacted]