PROTOCOL

Post Approval Study: Extended Duration Monitoring of Subjects with the Cochlear™ Nucleus® Hybrid™ L24 Cochlear Implant System

P130016

CAM-5563-HYB-PMA

Version 4

September 9, 2014

Study Sponsor:

Cochlear Americas

13059 East Peakview Avenue

Centennial, CO 80111

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This protocol contains confidential proprietary information with respect to Cochlear products and clinical trials. I agree to hold this information in confidence and not to disclose it to any third parties for the shortest of the following periods of time: three years from the date of this agreement, the time at which this information becomes a matter of public knowledge, or the time at which a formal agreement for that purpose has been entered into by the parties.

1 Investigator Responsibilities

I, the undersigned, am responsible for the conduct of the study at the site below and by my signature below, I confirm that I have read, understand and will strictly adhere to the study protocol, “Post Approval Study: Extended Duration Monitoring of Subjects with the Cochlear Nucleus® Hybrid™ L24 Cochlear Implant System.”

Clinical Investigational Site

Primary Investigator’s Name (print)

Title

Signature

Sponsor Representative

Title

Signature

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3 Clinical Investigational Synopsis

Title	**Post Approval Study: Extended Duration Monitoring of Subjects with the Cochlear Nucleus® Hybrid™ L24 Cochlear Implant System**
Study Sites	Up to 10 sites from the pivotal IDE (G070191)
Study Duration	3-5 years
Study Time	5 years post-activation for each subject
Study Population	Up to 35 subjects from the original pivotal IDE (G070191) and associated Continued Access IDE supplement who remain implanted with Hybrid L24 Implant, enrolled in the study, and have not met their 5 year post-activation interval as of the date of this submission
Design Overview	A prospective, multicenter, non-controlled, non-randomized study
Primary Objective	To evaluate the long term safety and effectiveness of the Nucleus Hybrid L24 Implant in implanted subjects out to 5 years post-activation
Study Intervals	Baseline2 years post-activation (if not yet completed) 3 years post-activation (if not yet completed) 4 years post-activation (if not yet completed) 5 years post-activation (if not yet completed)
Primary Safety Endpoint	Report of medical/surgical and device related adverse events consistent with those from the pivotal IDE with regard to type, frequency and seriousness
Primary Effectiveness Endpoint	Report of clinical performance using an open set monosyllabic word recognition measure in quiet and open set sentence measure in noise over the 5 year study period

4 Terms, Definitions, and Abbreviations

Term/Abbreviation	Definition
Acoustic Stimulation	Pre- or postoperative condition referring to the use of acoustic hearing alone, with or without amplification
Acoustic Component (AC)	An optional component for the sound processor used with the Hybrid L24 implant which provides amplification in the low frequencies for those patients who have residual hearing sensitivity postoperatively
AzBio Test[1]	A sentence level speech recognition test delivered in background noise at a predetermined signal to noise ratio
Bilateral Acoustic Stimulation	Preoperative condition referring to the use of bilateral acoustic hearing, with or without amplification
Bimodal Mode	Use of acoustic hearing, with or without amplification, in addition to electric hearing via a cochlear implant or Hybrid implant in the contralateral (opposite) ear.
BTE	Behind-The-Ear
CI	Cochlear Implant
CNC Word Recognition Test[2]	Consonant-Nucleus-Consonant Test: A monosyllabic word-level test given in quiet and calculated both as a word correct score and a phoneme correct score
Cochlear Implant Alone	Stimulation delivered by the Hybrid L24 implant alone.
Combined Mode	Use of acoustic hearing bilaterally, with or without amplification, in addition to electric hearing via a cochlear implant or Hybrid L24 implant
CRF	Case Report Form
Device Use Questionnaire (DUQ)	"In-house" device usability metric, administered to determine subjective preference and satisfaction with regards to device use in various listening environments
Electronic Data Capture (EDC)	
Everyday Listening Condition	Postoperative listening condition referring to either Combined Mode or Bimodal Mode
HL	Hearing Loss/Hearing Level
Hybrid Mode	Combination of acoustic and electric hearing in the same ear

[1] Spahr, A, Dorman, M., Litvak, L, Van Wie, S, Gifford, R *et al.* (2012). Development and validation of the AzBio sentence lists. Ear Hear 33(1): 112-117.

[2] Consonant-Nucleus-Consonant Test; Peterson, F.E. & Lehiste, I. (1962). Revised CNC lists for auditory tests. Journal of Speech and Hearing Disorders, 27(1): 62-70.

MAP	A program that defines the individualized fitting parameters of recipients for a specific coding strategy.
National Acoustic Laboratories (NAL)	Refers to a procedu8re for appropriately fitting hearing aids
Nucleus Custom Sound	Clinical programming software for Nucleus Implant Systems
Nucleus Sound Processor	BTE sound processor that is used to provide electric only or electric plus acoustic information when used in the Hybrid Mode
Signal-to-Noise Ratio (SNR)	The level relationship (ratio) of the target (signal) to the noise (e.g., if the target speech is 65 dBA and the noise is 60 dBA then the SNR = +5 dB)
Speech, Spatial, and Qualities of Hearing Scale (SSQ)	A validated metric used as a self-assessment of hearing in everyday life across three hearing domains: speech hearing, spatial hearing, and qualities of sound

5 Background

5.1 Regulatory History

The Hybrid L24 Implant System (P130016) was the subject of a pivotal clinical trial (IDE G070191) from 2007-2012. Data on the 50 subjects enrolled in the study in support of safety and efficacy of the device was submitted in June 2013 as part of PMA #130016. As part of the PMA approval, a Post Approval Study to monitor the long-term (5 years) safety and effectiveness of the device in this existing cohort of implanted subjects was designed.

5.2 Device Description

The Nucleus Hybrid L24 cochlear implant system consists of the following core components:

- Nucleus Hybrid L24 cochlear implant,
- Nucleus Sound Processor, and
- Nucleus Custom Sound™ programming software

5.2.1 Nucleus Hybrid L24 Cochlear Implant

The Nucleus Hybrid L24 Cochlear Implant to be evaluated in this study is the same as that used in the pivotal IDE study (#G070191). There have been no changes to this internal system component.

5.2.2 Nucleus Sound Processor

The current sound processor to be used in this clinical study, the Cochlear Nucleus 6 Sound Processor, is a BTE processor (Figure 1), with a modular design that incorporates a main signal processing module (the “sound processor”) with built-in directional microphones, a battery module (2 zinc air or rechargeable), radio frequency (RF) coil and coil cable. This sound processor was developed to provide acoustic (optionally) and electrical stimulation to hearing-impaired candidates who have some low-frequency residual hearing. The Nucleus 6 Sound Processor is functionally equivalent to the previous generation Freedom Hybrid Sound Processor. It is the commercially available sound processor for recipients of all current Nucleus cochlear implants, including the Hybrid L24 implant, at the time of study initiation.

Figure 1: Labeled components of the Nucleus 6 Sound Processor

Due to the long duration of follow up required for this Post Approval Study it is possible that new sound processor technology may be introduced during the course of this clinical study. If new technology is released, is proven to be functionally equivalent to the Nucleus 6 Sound Processor, and demonstrates performance at least as good as that from the Nucleus 6 sound processor, subjects may be given the option to upgrade to the new technology as part of this investigation.

5.2.3 Acoustic Component

Acoustic stimulation is delivered via an acoustic module, called the Acoustic Component. The Acoustic Component (Figure 2) connects to the sound processor to deliver acoustic amplification in a similar way to that from a conventional hearing aid. The retention of the Acoustic Component to the ear can be either via a custom earmold or a non-custom dome. Programming of the sound processor and the Acoustic Component is achieved via Custom Sound™ software.

Figure 2: Nucleus 6 Sound Processor with Acoustic Component. Shown is the dome retention system. The Acoustic Component can also be used with a custom earmold.

5.3 Custom Sound Clinical Programming Software

Programming of the sound processor is achieved via Custom Sound™ software. Custom Sound permits the characterization of both electric and acoustic parameters required for Nucleus 6 Sound Processor programming. The general approach for the electric programming is the same as that for traditional cochlear implant recipients except that the software provides more flexible frequency boundary assignments for the 22 channels of the Nucleus Hybrid L24 cochlear implant. The software provides the ability to specify the cut-off frequency at which acoustic stimulation ends and electrical stimulation begins. In addition, the software provides a user interface for the clinician to program amplification characteristics (gain and maximum output, frequency by frequency) for the subject's low-frequency range of hearing.

6 Indications for Use

All subjects met the following indications when enrolled under IDE G070191. Therefore, this section is for informational use only.

The Cochlear Nucleus Hybrid L24 Implant System is indicated for unilateral use in patients aged 18 years and older who have residual low frequency hearing sensitivity and severe to profound high-frequency sensorineural hearing loss, and who obtain limited benefit from appropriately fit bilateral hearing aids.

- Typical pre-operative hearing of candidates ranges from normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60dB HL up to and including 500 Hz), with severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75dB HL), and moderately sever to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 60dB HL) in the contralateral ear.
- The CNC word recognition score will be between 10% and 60% inclusively, in the ear to be implanted in the pre-operative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.
- Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fitted with hearing aids.

A Cochlear Nucleus Hybrid L24 cochlear implant is not indicated for individuals who have the following conditions:

1. Deafness due to lesions of the acoustic nerve or central auditory pathway
2. Active middle ear disease, with or without tympanic membrane perforation
3. Absence of cochlear development
4. A duration of severe to profound hearing loss of 30 years or greater.

7 Purpose of Study

The purpose of the Post Approval Study: Extended Duration Monitoring of Subjects with the Cochlear Nucleus Hybrid L24 Cochlear Implant System is to gather long term safety and effectiveness data on subjects implanted as part of the pivotal IDE (G070191). This real world experience may allow us to learn about sub-groups of patients, evaluate training programs, and further explore the type and frequency of adverse events beyond that which could be captured during the original clinical trial.

8 Study Objective and Hypothesis

The objective of this study is to collect long term (5 years) safety information and measures of device effectiveness on those subjects already enrolled in the pivotal Hybrid L24 IDE (G070191).

The study hypothesis will be that mean performance with the speech perception measures described below will show significant benefit with use of the Hybrid L24 implant, both in the implant ear and when using both ears together, over the 5 year study period when compared to the preoperative amplification condition.

9 Study Design

This Post Approval Study - Extended Duration Monitoring of Subjects with the Hybrid L24 Cochlear Implant System will be conducted as a repeated-measures, single-subject experiment. A single-subject research design (in which each subject serves as his or her own control) is appropriate since it accommodates the heterogeneity that characterizes hearing-impaired populations. Blinding or masking procedures are not included in the design as this population already has the Nucleus Hybrid L24 Implant System. It is not possible to conceal the presence or absence of the implant from device recipients and/or clinical investigators. To minimize order effects and test bias, word and sentence lists assigned to the various test conditions will be randomized across conditions, and the order in which test conditions are completed will be randomized.

This protocol is slightly revised from the original protocol under the pivotal IDE. Some measurements and test conditions that will not provide novel information have been removed to increase compliance with a 5 year protocol.

10 Study Population

Up to 32 subjects from the original pivotal study (G070191) population for the Hybrid L24 implant will be invited to participate. These subjects remain enrolled in the study, implanted with a Hybrid L24 device and have not reached their 5 year post-activation interval as of the date of this submission. All study subjects will have met the inclusion/exclusion criteria required for participation in the pivotal IDE. An additional group of 3 subjects who were enrolled in the Hybrid L24 Cochlear Implant System – Continued Access clinical trial (G070191/S024) will be invited to participate in this Post Approval Extended Duration study once the 12 month endpoint has been achieved according to the pivotal IDE protocol.

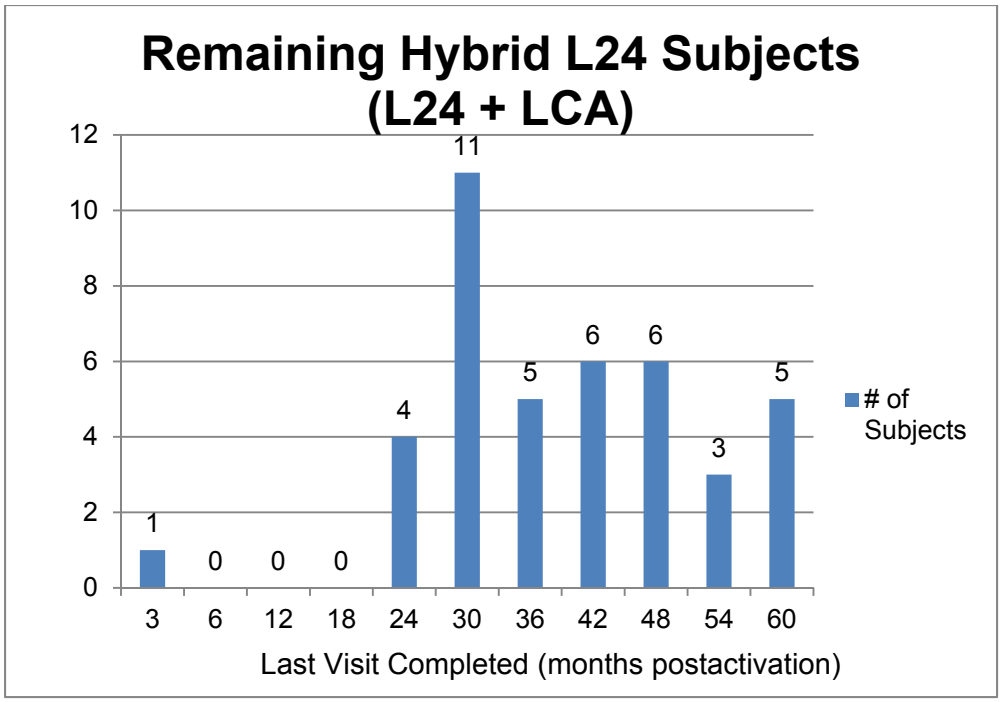

Figure 1: Enrolled Hybrid L24 Subjects

11 Inclusion/Exclusion Criteria

All subjects currently enrolled in the pivotal IDE study who remain implanted with a Hybrid L24 Cochlear Implant(G070191) and have not yet reached their 5 year postactivation interval will be invited to participate in this Post Approval Study – Extended Duration protocol. The only applicable exclusion criterion that could prevent participation is an unwillingness or inability of the subject to comply with all investigational requirements.

12 Primary and Secondary Endpoints

12.1 Safety Endpoints

12.1.1 Primary Safety Endpoint

The primary safety endpoint will be the comparison of the type and frequency of adverse events and serious adverse events occurring over the course of this study up to the 5 year post-activation interval as compared to the pivotal clinical study (G070191) for the Hybrid L24 implant.

12.1.2 Secondary Safety Endpoint

Secondary safety endpoints will include the following:

- Cumulative Safety Assessment: Adverse events with start dates prior to initial activation and each follow-up time interval will be tabulated.
- Procedure-Related Adverse Event Assessment: Procedure-related events occurring during the follow-up period will be tabulated.
- Device-Related Adverse Event Assessment: Device-related events occurring during the follow-up period will be tabulated.
- The above two classes of events (procedure and device related) will be summarized as rates. The numerator for each rate will be the number of subjects with at least one procedure (or device) related adverse event. The denominator will be the total number of subjects.
- Rates (overall and procedure and device related) will also be summarized by type.
- Time to first adverse event (including total losses of residual hearing) will be summarized using Kaplan Meier plots. Exploratory proportional hazards regression models will be used to determine whether demographics and baseline characteristics are associated with risk for adverse events over follow-up. Hazard ratios and 95% confidence intervals for these analyses will be cited.

12.2 Co-Primary Efficacy Endpoints

The co-primary efficacy endpoints for this study will be the assessment of statistical significance of the within-subject differences for two speech recognition tests, measured in two conditions: the implant ear and both ears:

- Word recognition in quiet as evaluated with the Consonant-Nucleus-Consonant (CNC) test (Peterson and Lehiste, 1962);
- Sentence recognition in noise (+5dB SNR) as evaluated with the AzBio test (Spahr et al., 2011)

Scores on both speech tests will be obtained at the study baseline (time of enrollment) and annually thereafter until study completion, 5 years from the initial activation of the device.

In an attempt to standardize speech assessment methods across commercial implanting centers, the above metrics were chosen based on the Minimum Speech Test Battery (MSTB) published in 2011 as a joint effort of the cochlear implant industry and the audiologic/otologic professional community. These test materials are provided free of charge to any cochlear implanting center and include calibration and instructions for use.

A secondary effectiveness analysis will be performed on the per-protocol population, which includes all randomized subjects who completed 5 years of follow-up with no major protocol violations.

13 Study Duration

Subjects will be followed to a point in time corresponding to 5 years post initial activation of the Hybrid L24 cochlear implant system. The majority of subjects who enroll in this study will have already met a number of data intervals past the 6 month primary end point in the pivotal IDE. Therefore, after a baseline evaluation, which will be completed for all enrolled subjects from the pivotal IDE who consent to participate regardless of their current time post initial activation, each subject will start at the appropriate test interval relative to his or her own initial activation date.

The total expected duration of this study is 3-5 years which includes time for all enrolled subjects to reach their 5 year post-initial activation endpoint. The target retention rate is at least 80% at 5 years. All efforts will be put forth to ensure near complete follow-up, with particular focus on assessment of the primary outcome and occurrence of adverse events. Regular reminders of subject follow up due dates will be provided to participating centers to facilitate scheduling of follow-up visits. In the event that a follow up due date is missed, the Sponsor will instruct the participating center to make three attempts to contact the study subject and inform them of the need to be tested. The third and final attempt will be in writing and if not response is received then the subject will be considered lost to follow up.

14 Overview of Study Procedures

Speech perception testing will be completed using the implant ear (hybrid mode or electric only) and both ears together (combined or bimodal mode). The specific test mode will depend on whether a subject has retained functional residual acoustic hearing sensitivity. In addition, subjects will be asked to complete subjective questionnaires to measure device use and satisfaction, and the degree of preservation of low-frequency hearing will be assessed as part of the safety data at each study interval.

Subjects will remain in the study for five years or until the Sponsor formally closes the study. Non-study follow-up evaluations may also take place at the discretion of the study site as part of routine care (e.g., to address device programming needs).

This protocol is slightly revised from the original protocol under the pivotal IDE. Some measurements and test conditions that are considered to not provide novel information have been removed to increase compliance with a 5 year protocol.

15 Investigational Procedures

15.1 Subject Identification

To maintain confidentiality, the subject's name will not be recorded on any study document other than the Informed Consent Form. All individuals who provide informed consent (who sign the Informed Consent form), are considered to be consented into the study and will use the unique identifier assigned to them. A unique alphanumeric code will identify the subject throughout the course of the study. For example, US01-HED-0000, where:

- US = United States
- 01 = a sequential number corresponding to the order in which a subject is enrolled into the study for a given study site
- HED = an abbreviation for the study, in this case HED for Hybrid Extended Duration
- 0000 = a unique, numeric study site identification

15.2 Release of Medical Information

The subject must sign a release that authorizes access of medical records to the study sponsor, investigators, monitors, and the Food and Drug Administration (FDA), prior to proceeding with any screening evaluations.

15.3 Informed Consent

The risks and benefits of participating in this study shall be explained to the subject as outlined on the Informed Consent Form. After reviewing the Informed Consent Form the potential subject will be given the opportunity to ask questions about the Informed Consent Form and/or the study prior to signing. The subject will then be given a copy of the signed Informed Consent Form.

Note: The Informed Consent document must be reviewed and signed by the relevant parties prior to any study-related evaluation taking place. Testing completed as part of normal clinical practice, such as the audiogram, is acceptable. However, such testing must be completed per the requirements laid out in the Procedures Manual and/or Case Report Forms (e.g., threshold measurement at inter-octave frequencies).

15.4 Description of Test Measures

15.4.1 Audiometric Assessment

Unaided audiometric thresholds will be obtained for each ear, with insert earphones, using the standard audiometric technique for pure-tone air conduction testing (refer to Appendix A for required specifications and calibration requirements).

Testing, for both ears, will include the following:

- Air conduction thresholds: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000Hz;

- Bone conduction thresholds: 250, 500, 750, 1000, 1500, 2000, 4000Hz

Note: Clinician will need to confirm the subject's response to any pure tone stimulus presented at 125 and 250Hz as auditory "heard" versus vibrotactile "felt" and record the response accordingly.

If the subject demonstrates preserved low frequency hearing in the implanted ear aided audiometric thresholds will be obtained for each ear in the sound field using narrow band noise and the standard audiometric technique with the speakers positioned at 0° azimuth relative to the subject's head.

- Aided thresholds at 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000Hz
- Tympanometry in each ear

If any significant change in unaided thresholds is noted then the amplification fitting(s) should be re-evaluated and adjustments made if necessary. A significant change for this purpose only is defined as a shift of more than 10dB (for the better or worse) at two or more aidable (i.e., those frequencies where thresholds are < 90dB HL) frequencies.

Note: As these subjects may have measureable low-frequency hearing, it is important that appropriate consideration be made for masking or plugging the contralateral ear during unilateral testing in the sound field. See Appendix B for details on masking procedure.

15.4.2 Speech Perception Assessment

15.4.2.1 Consonant-Nucleus-Consonant (CNC) Word Recognition Test

The CNC Word Test (Peterson & Lehiste, 1962) is a validated test used clinically and in research to assess the performance of adults with hearing aids or cochlear implants on open-set word recognition ability. The test consists of 10 recorded lists of 50 monosyllabic words in CD format. For this study, two lists will be administered in quiet at a level equal to 60 dBA in the sound field and scored as a total number of words correct, which will be expressed as a percentage correct for this study. Subjects will be tested using a configuration of speech at 0° azimuth.

15.4.2.2 AzBio Sentence Test

The AzBio Sentence Test (Spahr et al, 2012) is a validated test used clinically and in research to assess the open-set sentence recognition in speech-spectrum noise of adults with hearing aids or cochlear implants. It consists of 15 lists of 20 sentences each. AzBio sentences are spoken by different talkers in a conversational style with limited contextual cues that the listener can use to predict or 'fill in' unintelligible words. The sentences will be presented at a fixed level (65 dBA) in speech weighted noise at a fixed signal-to-noise ratio (+5 dB). Each list includes 5 sentences from each of 4 different male and female talkers. The average level of intelligibility

of each list is 85% +/- 1%. Each word in the sentence counts towards the overall score. Subjects will be tested using a configuration of speech and noise at 0° azimuth.

15.4.2.3 Test conditions

The following test conditions will be assessed for both CNC in quiet and AzBio in noise:

1. Implant (Hybrid mode or CI alone)
2. Everyday (Hybrid + Contralateral Acoustic or Bimodal)

Each subject's default MAP parameters, including rate of stimulation, number of maxima, and pulse width will be maintained for testing. The default Everyday signal processing algorithms (ASC +ADRO) will be utilized with all other signal processing algorithms turned off.

15.4.3 Subjective Questionnaires

15.4.3.1 Speech Spatial and Qualities of Speech Questionnaire (SSQ)

The SSQ (Gatehouse & Noble, 2004) will be used as a subject self-assessment in three categories (speech hearing rating scale, spatial rating scale, and sound qualities rating scale). The SSQ is considered a closed-ended self-report assessment of outcome.

15.4.3.2 Device Use Questionnaire (DUQ)

This questionnaire was developed by the Sponsor for use in the pivotal IDE and is used to collect information regarding device usability, subjective preferences, and satisfaction with regards to device use in various listening conditions.

15.5 Programming Follow-Up

The basic programming approach will be to assign frequency channels to the Hybrid electrode array that supplement the acoustic sensitivity. In other words, the frequency assignment of the electrical stimulation will begin at the frequency where acoustic hearing is no longer useful. For this purpose, hearing thresholds above 85dB HL will be considered not useful from an amplification perspective and not aidable acoustically. For example, if the subject's hearing in the implanted ear is more than 85 dB HL for frequencies at and above 1000 Hz (i.e., useful acoustic hearing up to 750 Hz), the lower frequency boundary for electric stimulation will be set as close as possible to 750 Hz (i.e., the last aidable frequency). That is, electrical stimulation would be provided in this case for inputs from around 750 to 8000 Hz and acoustic for frequencies at and below 750 Hz.

15.6 External Equipment Check

Prior to any speech perception testing, an assessment of the external hardware, including the Sound Processor and Acoustic Component, will be made. If any clinically significant change in

unaided thresholds is noted then the amplification fitting(s) will be re-evaluated and adjustments made if necessary.

15.7 Hearing Aid Verification

A hearing aid check will be completed by the clinician to verify that the contralateral hearing aid and the Acoustic Component for the Nucleus 6 Sound Processor in the implanted ear, if used, are functioning prior to aided testing.

If any significant change in unaided thresholds is noted then the amplification fitting(s) should be re-evaluated and adjustments made if necessary. As noted above, significant change for this purpose only is defined as a shift of more than 10dB (for the better or worse) at two or more aidable (i.e., those frequencies where threshold are < 90dB HL) frequencies. See Appendix C for additional information on fitting the contralateral hearing aid.

15.8 Psychophysical and Electrical Impedance Measurements

The following routine psychophysical and electrical impedance measurements will be obtained at the baseline evaluation as well as all annual post-activation intervals up to and including 5 years.

1. Electrical thresholds measured in Current Level on at least 5 channels per the streamlined fitting method
2. Electrical maximum comfort levels measured in Current Level on at least 5 channels
3. Impedance telemetry results using common ground (CG) and monopolar (MP1, MP2, and MP1+2) stimulation modes.

15.9 Interim Evaluation Intervals

Should a subject report a decrement in performance and should that decrement in performance not be directly related to a simple hardware problem, all specified interval testing will be conducted. Additionally, an otologic/medial case history will be taken.

16 Re-Implantation with a Long Electrode

16.1 Evaluation PRIOR to Re-implantation with a Long Electrode

As of July 8, 2014 six of the fifty subjects implanted under the pivotal IDE have elected to have the Nucleus Hybrid L24 cochlear implant removed and replaced with a standard, long electrode array cochlear implant. This has typically been in cases where individuals have experienced a profound or complete loss of residual hearing. Information about these six individuals has previously been reported to the FDA at the ENT Devices Panel meeting held on November 8, 2013. There have been no additional explantations since that time.

In order to ensure that accurate information is gathered for any subject electing to undergo explantation and re-implantation with a long array, additional data will be collected prior to re-implantation. This evaluation will include the following information and will follow the procedures described in the annual evaluation schedule:

- Audiometric testing
- Speech perception testing
- Psychophysical and electrical impedance measurements
- Otologic/medical questionnaire

If explantation occurs, in addition to being considered an anticipated serious adverse event, an MDR will be filed per 21 CFR Part 803.

16.2 Evaluation FOLLOWING Re-implantation with a Long Electrode

Subjects who elect to be implanted with a standard cochlear implant in the test ear in place of the Nucleus Hybrid L24 cochlear implant will be required to complete the study protocol as outline above. That is, they will be asked to follow the same postoperative schedule and procedures up to their 5 year post-activation interval.

17 Summary of Study Procedures

The following procedures will be completed at the baseline evaluation and then annually thereafter until the subject reaches the 5 year post-activation interval. Subjects who have already reached the 5 year interval will be seen for a one-time baseline evaluation where these same measures will be collected:

- Hearing aid verification and external equipment check
- Standard unaided audiometric threshold measures (insert earphones), for both ears
- Aided audiometric thresholds (implant ear)
- Tympanometry
- Speech perception testing for the implant ear alone and both ears together
    - CNC word recognition test in quiet at 60 dBA
    - AzBio sentences at 65 dBA in noise (+5 dB SNR)
- Subjective questionnaires of benefit
    - SSQ
    - DUQ
- Psychophysical measures and electrical impedance measures
- Impedance telemetry results using common ground (CG) and monopolar (MP1, MP2, and MP1+2) stimulation modes

Table 1: Summary of Data Collection Visits

	Baseline Evaluation	2 Years Post IA	3 years Post IA	4 Years Post IA	5 Years Post IA
Informed Consent	X				
HA Check/ AC Verification	X	X	X	X	X
Unaided Hearing Thresholds	X	X	X	X	X
Tympanometry	X	X	X	X	X
Aided Audiometric Thresholds	X	X*	X*	X*	X*
Processor Hardware Check	X	X	X	X	X
CNC test (Implant Ear and Both Ears)	X	X	X	X	X
AzBio-at +5dB SNR (Implant Ear and Both Ears)	X	X	X	X	X
DUQ	X	X	X	X	X
SSQ	X	X	X	X	X

**Note: Aided audiometric thresholds will be required at each annual interval so long as unaided hearing has been preserved at the time of testing.*

18 Adverse Events

For purposes of this protocol, Adverse Events (AE) reporting will be consistent with complaint reporting for similar approved technologies under 21 CFR 820.198 as the Nucleus Hybrid L24 cochlear implant is an approved device. The sponsor expects an increase in the percent of AEs reported per the installed base given the required reporting under this protocol.

As for loss of hearing sensitivity at the implant ear, these data will be trended in a similar fashion to the pivotal protocol (G070191) but will not be considered an adverse event unless the loss reaches a profound level (PTA average of 90 dB or greater for frequencies 125-1000Hz), total loss and/or explantation. Should an explantation occur, the sponsor will treat this as a serious injury with reporting occurring under the Medical Device Reporting regulations (21 CFR Part 803) in addition to inclusion in the annual update report on the Post Approval Study.

An Adverse Event (aka Adverse Effect or AE) is the development of an untoward medical occurrence or the deterioration of a pre-existing medical condition following or during exposure to an investigational product, whether or not considered causally related to the product or the surgical procedure to implant it. An untoward medical condition can be symptoms (e.g., nausea), signs (e.g., tachycardia, fever) or clinically significant abnormal results of an investigation (e.g., laboratory findings, chest x-ray).

Adverse events that occur during this study may be associated with the implant procedure, including those from general anesthesia, or specifically associated with the use of the device. An adverse event will be considered to be device-related when, in the judgment of the Primary Investigator, there is a logical connection between the use of the device and the occurrence of the event, above and beyond the study procedure itself. Adverse events associated with cochlear implantation in previous investigations include tinnitus, dizziness, swelling, facial nerve stimulation, and open and/or short circuit electrodes, among others.

A **Serious Adverse Event (SAE)** is any untoward medical occurrence which:

- Results in death;
- Is life-threatening;
- Requires in-patient hospitalization for > 24 hours or prolongation of hospitalization which is not specifically required by the protocol;

- Results in permanent impairment of a body function or permanent damage to a body structure; or
- Requires medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

For any SAEs, if the Primary Investigator judges that there is a logical connection (caused or contributed to) between the use of the device and the occurrence of the event, the event will be evaluated for reporting requirements under 21 CFR 803 and reported as an MDR if applicable.

An **unanticipated adverse device effect** (UADE) is "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects" [FDA 21 CFR 812.3(s)]. The Sponsor will promptly conduct an investigation upon notification by an Investigator of a UADE and will notify the FDA and all reviewing IRBs and participating Investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter, the Sponsor will submit such additional report concerning the effect as requested by the FDA.

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18.1 Assessment and Reporting of Adverse Events

18.1.1 Investigator's Responsibilities

Throughout the course of the study, all efforts will be made by the Investigators to remain alert to possible AEs. The first concern will be the safety and welfare of the subject and for providing appropriate medical intervention, as indicated. Detailed information regarding adverse events (AEs) will be recorded by the Investigator at the time an adverse event occurs using an *Adverse Event Questionnair*e, provided as part of the Case Report Forms (CRFs) for the study. All adverse events will be recorded from the day of enrollment (Day 0) to termination of study or when the subject exits the study, whichever is last, even if the event was acknowledged as a risk factor in the *Informed Consent Form*.

AEs will be recorded on an *Adverse Event Questionnaire* and will include the following information:

- Date of onset
- Date reported to the investigational site
- Description of the AE

- Seriousness
- Investigator's assessment of the relationship of the AE to the device and/or procedure
- Treatment
- Outcome

18.1.2 Unanticipated Adverse Device Effects

Unanticipated adverse device effects (UADEs) must be reported directly to the clinical center's reviewing IRB and the Sponsor, Cochlear Americas, within 10 working days of knowledge of the event, or as dictated by the specific IRB policy, whichever is sooner. Information regarding the UADE will be recorded on the *Unanticipated Adverse Device Effect Report,* provided with the CRFs for the study.

18.1.3 Adverse Event Follow-up

All AEs must be followed until resolution, or until the condition stabilizes. The Investigator is responsible to ensure that follow-up includes any supplemental investigations as may be indicated to elucidate as completely as possible the nature and/or causality of the AE. This may include additional laboratory tests or investigations, or consultation with other health care professionals. Cochlear or its designee may request that the Investigator perform or arrange for the conduct of supplemental measurements and/or evaluations. AE follow up information will be recorded using a *Follow Up to a Previously Reported Adverse Event Questionnaire,* provided with the CRFs for the study.

18.1.4 Sponsor's Responsibilities

All AEs will be reported annually to FDA in accordance with the IDE regulation [FDA 21 CFR Part 812.150(b)(5)]. All unanticipated adverse device effects (UADEs) will be reported to FDA within 10 calendar days of the event in accordance with FDA 21 CFR Part 812.46(b) and 812.150(b)(1) as well as 21 CFR 803.

Cochlear Americas or its designee will notify all participating Investigators of any new information that alters the current risk-benefit assessment of the study device or that would be sufficient to consider changes in management of the Nucleus Hybrid L24 cochlear implant or in the overall conduct of the trial.

19 Protocol Deviations

A protocol deviation refers to a study-related activity that is not in compliance with the investigational protocol. Deviations that are required to protect the life or well-being of a subject

do not require prior approval from the Sponsor and should be implemented immediately. In these cases, the deviation must be reported to the IRB and Sponsor within 5 (five) days of the event.

If a subject is unable to return for follow-up before the closure of a study visit window (+/- 90 days for post-activation study visits), or if protocol-defined assessments or parts thereof are omitted or completed incorrectly, the event is to be noted on the Protocol Deviation Log provided to the Investigator in the study Regulatory Binder. Depending on the type or severity of the deviation the Investigator may be required to notify the IRB and/or Sponsor if the deviation impacts safety or performance of the subject or data integrity.

20 Study Completion

20.1 Completed Subjects

Each subject in the study will be considered completed when all assessments up to and including 5 years post-activation interval have been performed in accordance with the study protocol. To be considered a primary endpoint success, subjects must retain their originally implanted device.

20.2 Discontinued Subjects

Any subject may voluntarily discontinue the study at any time without prejudice. The Investigator may discontinue a subject from the study at any time if (s)he considers that remaining in the study compromises the subject's health or the subject is not sufficiently cooperative. In either event, reason(s) for discontinuation should be recorded on a study withdrawal form, provided as part of the CRFs for the study.

Possible reasons for study discontinuation include the following:

- AE necessitating discontinuation from the study
- The subject is lost to follow-up
- Voluntary decision to withdraw consent made by the subject[3]
- Investigator decision[4]

[3] Withdrawal of consent is defined as the subject's voluntary decision to revoke consent to continue participation in the study.

- Other reason

In case of a subject lost-to-follow-up, the Investigator must attempt to contact the subject (or relative/family contact) by phone, email or letter at least three times. If attempts are unsuccessful, the 'subject withdrawal' form is to be completed in the study file and reported, as appropriate, in required reports to the Sponsor, IRB and FDA.

20.3 Premature Study Termination

The Sponsor reserves the right to discontinue the study for any safety, ethical, or administrative reason at any time. Subjects already implanted with the device being studied will continue to be supported, independent of any decision made about study continuation.

21 Study Milestones/Timeline

Expected Date of Study Initiation	10/1/2014
Expected Monthly Number of Study Sites with IRB Approval	3
Expected Date of Initiation of Subject Enrollment	12/1/2014
Expected Number of Subjects Enrolled per Month	5
Expected Date for Subject Enrollment Completion	7/1/2015
Expected Date for Complete Follow-up for All Study Participants	4/1/2019

22 Data Analyses

[4] Subject withdrawal from the study is defined as an Investigator decision. The Investigator may elect to withdraw a subject from the study at any time if he/she considers that remaining in the study compromises the patient's health or if the Investigator considers the subject lost to follow-up.

Detailed Statistical Analysis for this study is addressed in detail in the document entitled "Statistical Analysis Plan for Post Approval Study: Extended Duration Monitoring of the Cochlear Nucleus Hybrid L24 Implant."

23 Sample Size Calculation

While there will be a parallel study involving a minimum of 100 newly implanted Hybrid L24 implant subjects in addition to the original pivotal IDE cohort of 50 subjects, safety and efficacy data will be available on a minimum of 150 subjects in total.

For characterizing the incidence of adverse events over time, such as the occurrence of low frequency hearing loss, a total of 150 subjects would provide a precision (defined as the half-width of a two-sided 95% confidence interval) of approximately 8.3% or smaller. This calculation is based on an exact binomial confidence interval. Additionally, speech performance can be well characterized with a cohort of 50 subjects as demonstration in the original Hybrid L24 PMA data. Further, with this planned sample size for the combined cohorts, speech performance data on between 50 and 150 subjects will provide a precision of between 4.7% and 8.2% based on a standard deviation of approximately 29% as observed in the Hybrid L24 PMA data for the change in CNC and AzBio scores from preoperative to 6 months.

23.1 Analysis of Safety

- Adverse Events and Serious Adverse Events will be expressed as events per patient –time.
- All adverse event rates will be reported as the number and frequency of events with corresponding 95% exact binomial confidence limits and the number of events per patient-time (e.g., events per 10 patient years), and compared to the adverse events from G07019 (Hybrid L24 pivotal study).
- Time to first adverse event (including total losses of residual hearing) will be summarized using Kaplan Meier plots. Exploratory proportional hazards regression models will be used to determine whether baseline factors are associated with risk for adverse events over follow-up. Hazard ratios and 95% confidence intervals for these analyses will be cited.

23.2 Analysis of Efficacy

The significance of the mean differences in speech recognition scores between preoperative and the post-implant interval will be analyzed using maximum likelihood based on repeated measures linear regression models. In particular, repeated measures mixed models with subject as a random effect will be used that accounts for the within-subject correlation, allowing for

comparisons between baseline and follow-up co-primary endpoints. The analyses will incorporate the available time intervals: baseline, 2 years post initial activation (IA), and annually up to 5 years post IA. Follow-up time intervals will be treated as categorical, thus no test score trajectory pattern will need to be captured by the models. If there is significant evidence that the assumption of normality does not hold (i.e., $p < 0.05$ from a Shapiro-Wilk test of normality), then ranked data will be used in the repeated measures models.

The secondary effectiveness analysis will be performed on the per-protocol population, which includes all randomized subjects who completed 5 years of follow-up with no major protocol violations.

23.3 Annual Review of Subject Characteristics

Both safety and effectiveness data will be reviewed on an annual basis to compare the characteristics of subjects who remain enrolled in the study versus those who were lost to follow up. Baseline covariates to be explored and compared with study outcomes, specifically hearing loss and effectiveness measures, include:

- age at implantation,
- gender,
- duration of hearing loss,
- duration of severe hearing loss,
- pre-operative speech perception score,
- pre-operative low frequency pure tone average
- post-operative speech perception score (CNC and AzBio Sentences) at the last evaluation
- type and frequency of adverse events
- distance from the implant center

24 Risk Benefit Statement

The Nucleus Hybrid L24 Implant System represents a new treatment option for a patient population that has few current therapeutic alternatives for high frequency sensorineural hearing loss. High frequency sound, crucial for speech discrimination, is provided electrically by the Hybrid L24 Implant while residual low frequency hearing is amplified by the acoustic component. The two modes of stimulation are processed and provided simultaneously by the externally worn Nucleus Sound Processor.

Subjects with high frequency hearing loss that participated in the pivotal Hybrid L24 clinical study (G070191) were able to combine both low frequency (acoustic) and high frequency (electric) information, from one or both ears, provided by the Hybrid L24 Implant System. Results indicated significant speech perception improvements in quiet and in noise when compared to preoperative performance. At the primary study endpoint (6 months post activation), 100% of subjects showed equal or greater speech perception performance when listening with both ears (Hybrid + hearing aid in the opposite ear); greater than or equal to 90% of subjects showed equal to or greater speech perception performance when listening in the Hybrid Mode (electric and acoustic in the same ear).

As documented in the pivotal IDE (G070191) study results, a percentage of individuals will lose their preoperative low frequency acoustic hearing subsequent to implantation of the Hybrid L24 Implant. This known risk is disclosed in the Hybrid L24 implant system labeling and is strongly recommended as an integral component of preoperative surgical and device counseling. Irrespective of the postoperative hearing status, most individuals can still be expected to receive substantial functional and speech recognition benefit on a daily basis when compared to their preoperative listening configuration of two hearing aids. The pivotal IDE study results also demonstrated the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

For those subjects consenting to participate in this Post Approval Study the probable benefits to health from use of the Hybrid device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.

To characterize the clinical significance of residual low-frequency loss and assess the benefit-risk profile of the Hybrid L24 implant, an analysis of subjects' co-primary efficacy endpoints will be performed based on splitting subjects by their degree of low frequency hearing loss. This will follow the analysis of the Hybrid L24 PMA data with subjects experiencing moderate, moderately-severe, or severe low frequency hearing loss (Group 1) and subjects experiencing profound or total low frequency hearing loss (Group 2) described separately for their long term speech performance.

25 Good Clinical Practices Statement

This trial will be conducted in compliance with all applicable U.S. Federal Regulations and Good Clinical Practice (GCP) standards. This trial will be conducted in compliance with the protocol as approved by the FDA and each Investigative Site's Institutional Review Board (IRB). Any deviations from the protocol will be reported to the Sponsor and in accordance with the IRB's institutional guidelines.

26 Access to Study Documents and Study Monitoring

The Sponsor will designate appropriately trained monitors to review the progress of this supplemental study and assure the quality and integrity of data accumulated. Clinical monitors, as representatives of the Sponsor, have the obligation to provide site qualification and initiation visits as well as regular site visits. All data generated and the source documents from which they originated are open to inspection by the Sponsor or its representative, the FDA, and other regulatory agencies.

27 Quality Control and Assurance

Sponsor employees and/or their contracted representatives utilize Standard Operating Procedures (SOP) designed to ensure that clinical study procedures and documentation are consistently conducted/prepared to the highest quality standards. Safety data adjudication will be conducted by the Sponsor's Chief Medical Officer, in accordance with these SOPs. These SOPs require compliance with federal regulations and Good Clinical Practice guidance.

28 Institutional Review Board

Prior to the initiation of the study, the Protocol, the Informed Consent Form, and other supporting documentation must be submitted to the Institutional Review Board (IRB) for approval after FDA conditional or final approval. A copy of the IRB approval letter for the Protocol, the Informed Consent, and the Investigator Agreement must be submitted to the Sponsor prior to the consent of the first subject. The study site must maintain an accurate and complete record of all reports, documents, and other submissions made to the IRB concerning this protocol.

A list of the IRB members, their titles or occupations, and their institutional affiliation, or an IRB assurance number and their contact information must be provided to the Sponsor or its designee prior to release of study supplies. Additionally, the Chair of the IRB must be identified.

FDA/relevant health authority regulations require that all advertisements for subject recruitment be approved by an IRB prior to implementation. The complete text and format must be submitted to the Sponsor or its designee for approval prior to IRB submission.

29 Informed Consent Process

It is the responsibility of the Investigator to inform each subject prior to the initial study evaluation, of the purpose of this clinical trial, including possible risks and benefits, and document the informed consent process in the subject's chart.

A sample informed consent form containing the required elements of informed consent is provided by the Sponsor to the IRB once FDA approved. Any changes made to this sample by the IRB must be approved by the Sponsor, or its designee, prior to final submission to the IRB. After approval by the Sponsor, the final informed consent must be approved by the IRB. Prior to entry into the study or initiation of any study-related procedures, each subject must read, sign, and date the informed consent form. The person executing the consent must also sign and date the consent form. One original informed consent form is to be retained by the study site and a copy is to be given to the subject.

30 Confidentiality

In accordance with Good Clinical Practices (GCPs) and with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) all information concerning the subjects in the study must be treated as strictly confidential by all persons involved in the study.

The Investigator acknowledges that any and all information acquired from the Sponsor or its designee or developed or acquired in connection with the study are strictly confidential. The Investigator will not disclose any confidential information to any third party nor use confidential information for any purpose without first obtaining the consent of Sponsor in writing. Such consent shall be deemed to have been given for disclosure to any person for whom the Investigator is responsible at his/her center, but only so far as required for the purposes of the study, and, in the case of disclosures to staff, only if such staff are bound by obligations of confidentiality no less strict than those set out herein.

31 Protocol Amendments

The Sponsor will document modifications to the protocol in the form of a written amendment. Amended protocols must be acknowledged by Investigator signature and date upon receipt. Protocol modifications that impact subject safety or the validity of the study must be approved by the FDA and IRB before implementation. In the case of a medical emergency, to remove immediate apparent hazard to subjects, a change may be made preferably after discussion with the Sponsor or its designee. In these instances, the IRB and FDA will be notified as soon as possible.

32 Data Management

All study data will be entered into an Electronic Database Capture (EDC) system. Study personnel requiring access will have their own Login/Password. Access to clinical study information will be based on an individual's role and responsibilities. The application provides hierarchical user permission for data entry, viewing, and reporting options. For optimum security, all communications between the users and the EDC operate on a secured socket layer (SSL) using 256-bit encryption. The web servers are protected by a managed firewall from potential web and network attacks and the network is guarded by an intrusion detection and protection surveillance system against malicious threats.

As part of the data entry and validation process, the data stored in the EDC is checked against the source data, and also against edit check queries to confirm that the data received is within expected ranges. If any data is missing or is outside of expected limits, a query is created and sent to the site coordinator so that data may be verified and corrected. All changes made to a form are stored in an audit trail.

33 Record Keeping and Retention

Data generated for the study should be stored in a limited-access file area and be accessible only to representatives of the study site, the Sponsor and its representatives, and FDA/relevant health authorities/regulatory agencies. All reports and communications relating to study subjects will identify subjects only by subject unique identification code. Complete subject identification will be kept by the Investigator. This information will be treated with strict adherence to professional standards of confidentiality.

An Investigator must in reasonable time, upon request from any properly authorized officer or employee of FDA/relevant health authority or regulatory agency, permit such officer or employee to have access to requested records and reports, and copy and verify any records or reports made by the Investigator. Upon notification of a visit by the FDA, the Investigator will contact the Sponsor or its designee immediately. The Investigator will also grant Sponsor representatives the same privileges offered to FDA/relevant health authority or regulatory agents/officers/employees.

The Investigator must provide the Sponsor or its designee with the following documents at the time of site qualification and prior to study initiation and retain a copy in the site study file:

- Signed and dated curriculum vitae for the Principal Investigator
- A copy of the original approval for conducting the study by the IRB. Renewals, with continuance of the study, must be submitted at yearly intervals or as required by IRB policy and a copy of the approved and dated renewal provided to the Sponsor.

- A copy of the IRB approved informed consent form along with any modifications initiated by the Sponsor over the course of the study
- An IRB member list and Federal Wide Assurance (FWA) Number
- A signed Financial Disclosure Form for each Investigator
- An Investigator Agreement for this protocol signed and dated by each Investigator

In addition to the documents listed above, the study site will also retain the following items and make them available for Sponsor review upon request.

- Certifications, applicable study equipment (audiometers, etc.) calibration records and laboratory reference ranges for all local laboratories used for this study. The Sponsor will verify all equipment requirements at the study qualification and/or initiation. Sites with outdated and/or non-compliant equipment will either not be approved for study participation or will be advised to discontinue study-related activities should non-compliance be noted during regular study monitoring visits.
- All original informed consent forms with required signatures
- All IRB correspondence (i.e., informed consent [including any approved revisions], protocol, AEs, advertisements, newsletters)
- Copy of the Study Monitoring Log Sheet
- Clinical and non-clinical supply shipment forms and device accountability logs
- Copies of all correspondence pertaining to the study between Sponsor and the site
- Copies of all SAEs reports submitted to the Sponsor
- Copies of all FDA progress reports submitted to the site by the Sponsor
- Site Delegation Signature Log

All study-related records must be maintained for at least 2 years after a marketing application (PMA) is approved for the study device; or if the application is not approved, until at least 2 years after shipment and delivery of the last device for investigational use is discontinued and FDA/health authorities or regulatory agencies have been notified of study closure. The Sponsor will notify the principal Investigator when records are no longer needed. The Investigator will not discard any records without notifying the Sponsor. If the Principal Investigator moves from the current investigational site, the Sponsor should be notified of the name of the person who will assume responsibility for maintenance of the records at the investigational site or the new

address at which the records will be stored. The Investigator will notify the Sponsor as soon as possible in the event of accidental loss or destruction of any study documentation.

34 Reporting Requirements for Interim and Final Reports

Interim Post Approval Study Status Reports will be submitted to the FDA every 6 months for the first two years of the study and annually, thereafter. This schedule will continue for the duration of the study until the Final Post-Approval Study Report to be filed within 3 months after study completion.

Study Report and Publication

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.

The aggregate data resulting from this study will be the proprietary information of the Sponsor and may be made public after all data have been analyzed and the study results are available. None of the data resulting from this study will be allowed to be presented or published in any form, by the Investigator or any other person, without the prior written approval of the Sponsor. At the end of the study, a clinical study report will be written by the study Investigators or their designee and reviewed by the Sponsor.

35 References

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36 Appendix A: Procedural considerations

- All pre and postimplantation testing will be completed using an audiometer, such as a Grason Stadler GSI 61 (Grason Stadler, Inc., Milford, NH, U.S.A.) or equivalent, calibrated to American National Standards Institute (ANSI) standards with maximum output for frequencies of 0.5 to 4 kHz of no less than 120 dB HL.

- Speech and hearing evaluations will be completed in, at a minimum, a single-walled sound booth capable of accommodating a calibrated, 90-degree, speaker orientation.

- Stimuli will be administered using either insert earphones and/or sound field speakers. Applicable ANSI standards are: ANSI/ASA S3.6-2004; **ANSI S3.1-1999** (R 2003).

- Pure tone threshold exploration will be completed using the adaptive Hughson & Westlake procedure (1944).

- Sound field calibration will be completed as recommended by Katz (2002). The sound level meter should be set to the “A scale” and “slow” settings. The sound level meter will be placed in the center of sound booth, approximately 1m from the loud speaker face, at the height of which would represent the center of an average subjects head. The calibration noise (test specific, however preferably speech spectrum noise) will be administered through the audiometer output to the loud speaker within the sound booth. The sound level meter detects the audiometer output through the loud speaker. With the VU meter on the audiometer set to 0 while, the dial on the audiometer is adjusted until the sound level meter within the sound booth detects the desired output.

37 Appendix B: Instructions for Masking

1. Puretone threshold is established in the test ear.
2. Masking noise is introduced to the non-test ear at the initial masking level (10dB above the established threshold in the non-test ear). Puretone threshold then is re-established.
3. Level of the masking tone or noise is increased subsequently by 5 dB. If there is a response to the tone in the presence of the noise, the level of the noise is increased by 5 dB. If there is no response to the tone in the presence of the noise, the level of the tone is increased by 5-dB steps until a response is obtained.
4. A plateau has been reached when the level of the noise can be increased over a range of 15 to 20 dB without shifting the threshold of the tone. This corresponds to a response to the tone at the same HL when the masker is increased in three to four consecutive levels.
5. Masked puretone threshold corresponds to the HL of the tone at which a masking plateau has been established.

38 Appendix C: Hearing Aid Fitting Guidelines

Step 1 Create Hearing Aid Program

Method:

1. Using the hearing aid software, create a hearing aid program using the recipients' audiogram.

Step 2 Obtain Real Ear Unaided Response

Method:

1. Calibrate the probe tube.
2. Position the patient one meter in front of the speaker.
3. Place the probe tube in the ear canal approximately 25 to 30 mm past the tragal notch.
4. Select recorded speech at conversational level, 65 dBSPL.
5. Ensure the cochlear implant sound processor is turned OFF.
6. Using a prescriptive algorithm (e.g.,NAL-NL1 or NAL-RP), obtain REUR.

Step 3 Obtain Real Ear Aided Response

Method:

1. With the probe tube in place, insert the hearing aid. Ensure that it is ON and detected by the hearing aid software. Ensure the cochlear implant sound processor is turned OFF.
2. Select recorded speech at conversational level, 60 dBSPL.
3. Allowing for subjective report, adjust hearing aid software to match real ear target gain and maximum output.

Step 4 Balance hearing aid and cochlear implant loudness (if applicable)

Method:

1. With the hearing aid connected to the hearing aid software, turn the cochlear implant sound processor ON.
2. Select recorded speech at conversational level, 60 dBSPL.
3. Ask the patient to point to which side is loudest or if the sound is balanced.
4. Use the conversational recorded speech to adjust the gain in the hearing aid software as needed to balance the loudness the between the two devices.
5. Repeat for soft speech (50 dB SPL).
6. Adjust the compression ratio and/or compression threshold in the hearing aid as needed so that soft speech is audible and equal in volume.
7. Repeat for loud speech (85 dB SPL).
8. Adjust the maximum power output of the hearing aid as needed so that loud sounds do not exceed the patient's loudness discomfort level.