CLINICAL STUDY PROTOCOL

TITLE: **A Single-center, Retrospective Study to Evaluate the Clinical Performance of Artificial Intelligence Medical Assisted Diagnostic Software (VeriSee AMD) for Screening of Age-Related Macular Degeneration**

Protocol Number: AHCI21001

Phase of Study: Pivotal study

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Sponsor: Acer Medical Inc.

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Confidentiality Statement

Title:

A Single-center, Retrospective Study to Evaluate the Clinical Performance of Artificial Intelligence Medical Assisted Diagnostic Software (VeriSee AMD) for Screening of Age-Related Macular Degeneration.

Objectives:

This study is to evaluate the clinical performance of VeriSee AMD for AMD screening from color fundus photography images. The sensitivity and specificity of VeriSee AMD's automated image analysis for screening the age-related macular degeneration will be determined.

Investigational product:

1. Name: VeriSee AMD

2. Model: AMD-01

3. Manufacturer: Acer Medical Inc.

4. Method of analysis: VeriSee AMD is a software as medical device that incorporates an artificial intelligence (AI)-based algorithm to evaluate the age-related macular degeneration (AMD) from color fundus photography images screening. The screening result of AMD will be determined as non-more than level 3 AMD (non-mtl3AMD) or more than level 3 AMD (mtl3AMD).

5. Intended use: VeriSee AMD is intended to screen AMD from the images taken by color fundus photography, which can assist the physicians to assess whether further examination for retinopathy by the ophthalmologist is needed. The screening result of AMD will be determined as non-mtl3AMD or mtl3AMD. VeriSee AMD only provides the screening results of AMD for the physicians' reference and VeriSee AMD is not intended to diagnose of AMD, detect concomitant diseases, or treat AMD.

6. Device type: Software as a medical device (SaMD)

Endpoints:

1. Primary endpoint:

- To evaluate the clinical performance of VeriSee AMD by determining the sensitivity and specificity.

2. Secondary endpoints:

- To evaluate the clinical performance of VeriSee AMD by determining the positive and negative predictive values (PPV and NPV)
- To determine the percentage of subjects' images with insufficient quality as judged by VeriSee AMD

Selection criteria:

The screening by inclusion and exclusion criteria for eligibility of subjects will be performed by the information technology office at the clinical site. A dedicated ophthalmologist will be responsible to confirm the eligibility of enrolled subjects' color fundus photography images for inclusion criterion # 3 and exclusion criterion # 2.

1. Main inclusion criteria:

(1) Subject with age ≥ 50 years old

(2) Subject with image taken by Canon CR-2 that meet the following requirement:

- The resolution of image is 271×271 pixels or higher.
- The angle view of image is 45 or 50 degrees.

(3) Subject's image includes macula as judged by the ophthalmologist.

2. Main exclusion criteria:

(1) The color fundus photography image previously used by VeriSee AMD during the development process and pre-clinical test

(2) The macula or other part in the image of color fundus photography is unclear to determine the disease condition as judged by the ophthalmologist.

Study procedures:

This is a single-center, retrospective study to evaluate the performance of VeriSee AMD for screening of potential age-related macular degeneration (AMD). The sensitivity and specificity of VeriSee AMD will be determined in this study by comparing the results of gold standard, which is the judgment of AMD by the ophthalmologists (evaluators).

Age-Related Macular Degeneration Severity Scale (AMD Severity Scale)	
AMD Level	**Criteria**
1	Drusen maximum size < circle C-0 (63 μm diameter) and total area < circle C-1 (125 μm diameter)
2	Presence of one or more of the following: (a) Drusen maximum size ≥ circle C-0 but < circle C-1 (b) Drusen total area ≥ circle C-1 (c) Retinal pigment epithelial pigment abnormalities consistent with AMD, defined as one or more of the following in the central or inner subfields: (1) Depigmentation present (2) Increased pigment ≥ circle C-1 (3) Increased pigment present and depigmentation at least questionable
3	Presence of one or more of the following: (a) Drusen maximum size ≥ circle C-1 (b) Drusen maximum size ≥ circle C-0 and total area > circle I-2 and type is soft indistinct (c) Drusen maximum size ≥ circle C-0 and total area > circle O-2 and type is soft distinct (d) Geographic atrophy within grid but none at center of macula
4 (Advanced)	Presence of one or more of the following: (a) Geographic atrophy in central subfield with at least questionable involvement of center of macula (b) Evidence of neovascular AMD (1) Fibrovascular/serous pigment epithelial detachment (2) Serous (or hemorrhagic) sensory retinal detachment (3) Subretinal/subretinal pigment epithelial hemorrhage (4) Subretinal fibrous tissue (or fibrin) (5) Photocoagulation for AMD