I. Protocol Title:

A Single-center, Retrospective Study to Evaluate the Clinical Performance of Artificial Intelligence Medical Assisted Diagnostic Software (VeriSee DR) for Screening of Diabetic Retinopathy (DR) in Patients with Diabetes Mellitus.

II. Objectives:

This study is to evaluate the clinical performance of VeriSee DR for Diabetic Retinopathy from color fundus photography images. The sensitivity and specificity of VeriSee DR's automated image analysis for screening the DR will be determined.

III. Investigational products:

1. Name: VeriSee DR
2. Method of analysis: VeriSee DR is a software as medical device that incorporates an artificial intelligence (AI)-based algorithm to evaluate the Diabetic Retinopathy (DR) from color fundus photography images screening. The screening result of DR will be determined as referable DR or non-referable DR by VeriSee DR.
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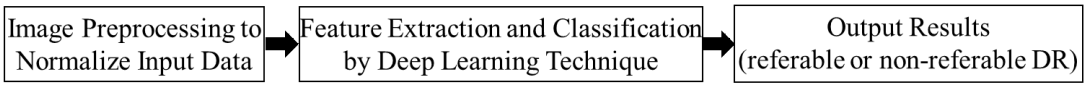

4. Intended use: VeriSee DR is intended to screen DR from the images taken by color fundus photography, which can assist the physicians to assess whether further examination for retinopathy by the ophthalmologist is needed. VeriSee DR only provides the screening results of DR for the physicians' reference and VeriSee DR is not intended to diagnose of DR or treat DR.
5. Device type: Software as a medical device (SaMD)

IV. Endpoint:

1. Primary endpoint:
   - To evaluate the clinical performance of VeriSee DR by determining the sensitivity and specificity.
2. Secondary endpoints:

- To evaluate the clinical performance of VeriSee DR by determining the positive and negative predictive values (PPV and NPV)

V. 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 # 4 and exclusion criterion # 2.

1. Main inclusion criteria:
   - Subject with age ≥ 20 years old
   - Subject with documented diagnosis of diabetes mellitus
   - Subject with image taken by color fundus photography that meet the following requirement:
     - The resolution of image is 1024×1024 pixels or higher;
     - The angle view of image is 45 or 50 degree.
   - Subject's image includes macula and optic nerve as judged by the ophthalmologist.
2. Main exclusion criteria:
   - The color fundus photography image previously used by VeriSee DR during the development process and pre-clinical test
   - The macula, optic nerve, or other part in the image of color fundus photography is unclear to determine the disease condition as judged by the ophthalmologist.

VI. **Study procedures:** This is a single-center, retrospective study to evaluate the performance of VeriSee DR for screening of potential diabetic retinopathy (DR). The sensitivity and specificity of VeriSee DR will be determined in this study by comparing the results of gold standard, which is the judgment of DR by the ophthalmologists (evaluators).

	International Clinical Diabetic Retinopathy Disease Severity Scale	
Stage	**Proposed Disease Severity Level**	**Findings Observable upon Dilated Ophthalmoscopy**
0	No apparent retinopathy	No abnormalities
1	Mild non-proliferative diabetic retinopathy (NPDR)	Microaneurysms only
2	Moderate NPDR	More than just microaneurysms but less severe NPDR
3	Severe NPDR	Any of the following and no signs of PDR • More than 20 intraretinal hemorrhages in each of 4 quadrants • Definite venous beading in 2 or more quadrants • Prominent IRMA in 1 or more quadrants
4	Proliferative diabetic retinopathy (PDR)	One of both of the following: • Neovascularization • Vitreous/preretinal hemorrhage