April 28, 2022

RetinAI Medical AG
Enisa Dresevic
Head of Quality and Regulatory Affairs
Freiburgstrasse, 3
Bern, 3010
Switzerland

Re: K211715
Trade/Device Name: RetinAI Discovery
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: March 25, 2022
Received: March 25, 2022

Dear Enisa Dresevic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211715

Device Name

RetinAI Discovery

Indications for Use *(Describe)*

The RetinAI Discovery is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports and measurements of DICOM-compliant images. The device is also indicated for manual labeling and annotation of retinal OCT scans.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

RetinAI Discovery

Submitter: RetinAI Medical AG
Freiburgstrasse 3
3010 Bern
Switzerland

Phone: +33 6 29 39 55 25
Contact Person: Enisa Dresevic

Date Prepared: April 27, 2022

510(k) number: K211715

Name of Device: RetinAI Discovery
Classification Name: Medical image management and processing system
Regulatory Class: II
Product Code: NFJ

Predicate Device

Optos PLC's OptosAdvance (K162039)

Reference Devices

Topcon DRI OCT Triton (K173119)
Heidelberg Engineering Spectralis (K173648)

Intended Use / Indications for Use

The RetinAI Discovery is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The device is also indicated for manual labeling and annotation of retinal OCT scans.

Device description

The RetinAI Discovery consists of a platform which displays and analyzes images of the eye (e.g. OCT scans and fundus images) along with associated measurements (e.g. layer thickness) generated by the user through Discovery. The platform allows the user to manually segment layers and volumes in the images, it calculates the layer thickness and volume from annotated images and presents the progression of the measurement in graphs. Discovery provides a tool for measuring ocular anatomy and ocular lesion distances. The multiple views in Discovery and the measurements allow the user to assess the eye anatomy and, ultimately, assist the user in making decisions on diagnosis and monitoring of disease progression.

Summary of Technological Characteristics

Both the subject and predicate device are standalone software devices intended to display and analyze previously-acquired images of the eye in order to streamline review of such images by healthcare professionals. Both devices are browser-based platforms that can be used on a variety of web browsers (i.e., Google Chrome, Mozilla Firefox, Microsoft Edge) and feature similar capabilities. The principal difference between the products relates to the availability in Discovery of a wider range of viewing layouts compared to the predicate device. A table comparing the key features of the subject and predicate devices is provided below.

The validation of RetinAI Discovery performance is supported by comparison testing with two Reference Devices, Heidelberg Engineering SPECTRALIS HRA+OCT (K173648) and Topcon DRI OCT Triton (K173119). While Discovery is a standalone, browser-based software application, the cleared devices selected as Reference Devices are imaging devices which include ophthalmic image management and data analysis software. The Heidelberg Engineering SPECTRALIS HRA+OCT (K173648) and Topcon DRI OCT Triton (K173119) offer automatic segmentation of retinal layers and measurement features, but also a manual segmentation tool, similar to the one included in the Discovery platform.

	RetinAI Discovery	**OptosAdvance (K162039) Primary Predicate Device**	**Topcon DRI OCT Triton (K173119) Reference Device 1**	**Heidelberg Engineering Spectralis (K173648) Reference Device 2**
Intended Use	RetinAI Discovery is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports, and measurement of DICOM-compliant images. The device	OptosAdvance 4.0 is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports, videos, and measurement of DICOM-compliant images.	The Topcon DRI OCT Triton is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions. The DRI OCT Triton is indicated for in vivo viewing, axial cross sectional, and	The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for: • viewing the posterior segment of the eye, including two- and three-dimensional imaging • cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT) • fundus imaging • fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT,

	is also indicated for manual labeling and annotation of retinal OCT scans.		three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures. It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The DRI OCT Triton is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.	SPECTRALIS HRA) • autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) • performing measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, including: • age-related macular degeneration • macular edema • diabetic retinopathy • retinal and choroidal vascular diseases • glaucoma The device is indicated for viewing geographic atrophy. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases: • a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian

				subjects • a reference database for retinal nerve fiber thickness and optic nerve head neuroretinal rim parameter measurements, which is used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values of normal subjects of different races and ethnicities representing the population mix of the USA (Glaucoma Module Premium Edition)
Product Code	NFJ	Same	OBO, HKI	OBO, MYC
User Population	Healthcare Professionals	Same	Same	Same
Technological Characteristics	Standalone software	Same	OCT device used in combination with Triton data analysis software	OCT device used in combination with Heyex data analysis software
Operating System	Browser-based	Same	Local installation of the software	Local installation of the software
Data and Supported Formats	DICOM-compliant files from an ophthalmic device, such as Fundus photographs, Optical Coherence Tomography (OCT) scans	DICOM-compliant files from an ophthalmic device (Scanning Laser Ophthalmoscope, Fundus Camera, Optical Coherence Tomography unit, etc.)	Images acquired from the Topcon OCT device	Images acquired from the Spectralis OCT device and DICOM-compliant files from an ophthalmic device

Supported Machines	DICOM-compliant devices	Integration with eyecare diagnostic devices via DICOM	Topcon	Spectralis and DICOM-compliant devices
Image Annotation and Measurement	Yes	Same	Data is automatically processed with analysis functions such as the automatic retinal layers segmentation, the automatic thickness calculation with several grids, the optic disc analysis and comparison with a reference database of eyes free of ocular pathology, and is finally automatically saved to the PC. It allows the user to manually adjust the automated retinal layer segmentation results and optic disc analysis results.	Data is automatically processed, segmentation of retinal layers and relative measurements are displayed in the interface through reports. It allows the user to manually adjust the automated retinal layer segmentation results
Sharing	Share images with current layout with another user via shareable link	Same	Sharing is not available	Drag-and-drop export sharing

Standards compliance

Discovery complies with the following standards:

Standards	Standards organization	Standards title
PS 3.1 - 3.20 (2021e)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set
62304 Edition 1.1 2015-06 Consolidated version	AAMI / ANSI / IEC	Medical device software - Software life cycle processes
82304-1 Edition 1.0 2016-10	AAMI / ANSI / IEC	Health software - Part 1: General requirements for product safety

14971:2019	AAMI / ANSI / ISO	Medical Devices - Application of risk management to medical devices
15223-1 Third Edition 2016-11-01	AAMI / ANSI / ISO	Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied - Part 1: General requirements

Regarding the compliance to the PS 3.1 - 3.20 (2021e) standard, RetinAI Discovery supports reading of DICOM objects obtained from Media Storage and File Format for Data Interchange PS 3.10 files loaded from the local file system or from PS 3.12 compliant media according to one of the General Purpose Media Application Profiles of PS 3.11.

Performance Data

Discovery was designed, developed and tested according to the software development lifecycle process implemented at RetinAI Medical AG, based on the IEC 62304 and IEC 82304 standards, and the FDA Guidance for the "General Principles of Software Validation". Testing included verification and validation activities (static code analysis, unit and integration testing, system and functional testing). In addition, comparison testing was performed to demonstrate the equivalence of the manual segmentation and image measurement of retinal OCT scans in Discovery platform, in both "Optimized" and "Device" display modes, with the same images segmented in cleared devices, Heidelberg Engineering Spectralis HRA+OCT (K173648) and Topcon DRI OCT Triton (K173119). The results showed that the computed values from the Discovery platform are substantially equivalent to the computed values from the Reference Devices, for both Optimized and Device display modes.
In all instances, Discovery functioned as intended and expected performance was reached.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could result in minor injury to the patient through incorrect or delayed information or through the action of a care provider.

Conclusions

The RetinAI Discovery performs in a manner that is substantially equivalent to the predicate device, OptosAdvance. The RetinAI Discovery has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the RetinAI Discovery and its predicate device do not raise different questions of safety or effectiveness. Thus, the RetinAI Discovery is substantially equivalent.