October 24, 2018

Carl Zeiss Meditec, Inc
Maria Golovina
Sr. Staff Regulatory Affairs Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K182318
Trade/Device Name: Retina Workplace
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ, OBO, HKI
Dated: August 17, 2018
Received: August 27, 2018

Dear Maria Golovina:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Alexander Beylin -S
2018.10.24 15:19:44 -04'00'

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182318

Device Name
Retina Workplace

Indications for Use *(Describe)*

The Retina Workplace is a FORUM application intended for processing and displaying fundus image and optical coherence tomography data. It is also intended for generating reports that contain results from optical coherence tomography and fundus photography.

The Retina Workplace uses CIRRUS algorithms and normative databases as a quantitative tool for the comparison of macular thickness data to a database of normal subjects. It supports the processing and displaying of CIRRUS OCT-Angiography data, which is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The Retina Workplace is intended to aid trained healthcare professionals in the detection, monitoring and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy and age-related macular degeneration.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

(as per 21 CFR §807.92)

Retina Workplace

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany +49 (0) 89 909 000-185 (phone) +49 (0) 89 909000-222 (fax) Establishment Registration Number: 9615030
Contact Person:	Maria Golovina Sr. Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 (925) 216-2184 Mobile (925) 557-4259 Fax E-mail: maria.golovina@zeiss.com

Date prepared:	October 22, 2018
Device	System, Image Management, Ophthalmic
Classification:	21 CFR 892.2050
Device Class:	II
Product Code:	NFJ
Common Name:	Picture Archiving and Communications System
Trade/Proprietary Name:	Retina Workplace

The Retina Workplace is intended to be a clinically focused accessory to the FORUM Workplace. The Retina Workplace as described in this premarket notification has a similar intended use, indications for use (specific for the device), and is based on the same fundamental scientific technical characteristics as the predicate devices listed below.

Substantial Equivalence Claimed To (21 CFR §807.92(a)(3))

Predicate Devices	**Clearance / Date**	**Company**
The Retina Workplace 2.0 is a clinically focused workplace for retina disorders and is accessory to the FORUM PACS system and is a client of the FORUM PACS server	K170638 / June 21, 2017	Carl Zeiss Meditec AG
FORUM® is a server based PACS system supporting generic post-processing tools (display, pan, zoom, generating reports, etc.) and interfaces with DICOM based ophthalmic devices.	K122938 / November 2, 2012	Carl Zeiss Meditec AG
CIRRUS™ HD-OCT (Version 8) containing algorithms for the detection and analysis of ophthalmic anatomy, including Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Reference Databases. It provides CIRRUS OCT-Angiography as aid to visualize the vascular structure of the retina and choroid.	K150977 / June 21, 2017	Carl Zeiss Meditec AG
CIRRUS™ Photo Combined fundus camera and OCT system for the imaging, display, storage, and report generation of the fundus images and OCT images.	K133217 / March 19, 2014	Carl Zeiss Meditec AG

INTENDED USE (21 CFR §807.92(a)(5))

The Retina Workplace is a FORUM application intended for processing and displaying image and optical coherence tomography data. It is also intended for generating reports that contain results from optical coherence tomography and fundus photography.

INDICATIONS FOR USE (21 CFR §807.92(a)(5))

The Retina Workplace is a FORUM application intended for processing and displaying fundus image and optical coherence tomography data. It is also intended for generating reports that contain results from optical coherence tomography and fundus photography.

The Retina Workplace uses CIRRUS algorithms and reference databases as a quantitative tool for the comparison of macular thickness data to a database of normal subjects. It supports the processing and displaying of CIRRUS OCT-Angiography data, which is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The Retina Workplace is intended to aid trained healthcare professionals in the detection, monitoring and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy and age-related macular degeneration.

The Retina Workplace (version 2.5) is intended for prescription use only.

DEVICE DESCRIPTION (21 CFR §807.92(a)(4))

The Retina Workplace is designed in conjunction with the FORUM PACS system, which support clinically focused client workplaces to aid the optometric and ophthalmology clinicians with the processing, display, review, management, and storage of digital data contained in patient records. The Retina Workplace is software application of FORUM Archive and Viewer PACs workplace. FORUM is a software system designed for storage, processing, and review of images, videos, and reports originating from computerized diagnostic instruments or electronic documentation systems over a network. The Retina Workplace is connected to the FORUM server via an internal interface. The Retina Workplace retrieves CIRRUS OCT exam data and fundus images from the FORUM server. The Retina Workplace is intended to support the physician with a clinically focused workplace for the retina by using the imported OCT exam data from CIRRUS HD-OCT and CIRRUS Photo to report and display the results.

The Retina Workplace (version 2.5) is the latest generation device in the Retina Workplace series. The version of the 2.5 that is the subject of this submission is a modified version of the Retina Workplace (version 2.0) cleared under K170638.

Like its predecessors, Retina Workplace version 2.5 is designed to process and display CIRRUS OCT exams by using the algorithms and databases that are currently in use on the FDA cleared CIRRUS HD-OCT version 8 (K150977) and CIRRUS Photo (K133217). The CIRRUS HD-OCT OCT-Angiography was also cleared in K150977.

RISK MANAGEMENT AND GENERAL SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary caution and notes, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements, and validation of the clinical workflow to ensure that the product meets its intended uses. ZEISS adheres to recognized and established industry practice and relevant international standards where indicated.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE (21 CFR §807.92(a) (6)):

The Substantial Equivalence comparison chart demonstrates the comparison of the technological characteristics of the Retina Workplace to the currently cleared predicate devices.

Table 1. Technological Comparison Summary Retina Workplace (version 2.5 – K182318) to Retina Workplace (version 2.0 – K170638)

Description	Predicate	Subject
Support for CIRRUS OCT-Angiography	N/A	X
Compatibility with FORUM PACS system	X	X
Processing of clinically focused OCT exam results from CIRRUS HD-OCT and CIRRUS photo	X	X
Display of exam results in relation to reference data and have similar workflows	X	X
Use of same algorithms and reference databases to perform evaluations of ophthalmic condition analysis and change analysis as well as the generation of ETDRS grids	X	X
Registration of images generated by Fundus photography to OCT fundus images and LSLO fundus images generated by CIRRUS HD-OCT devices	X	X
Support automatic registration to compensate for the differences in scan location during acquisition	X	X
Support of Macular Thickness Analysis, Macular Change Analysis, and Advanced RPE	X	X
Support en face analysis VRI, Mid-Retina, IS/OS Ellipsoid, Choroid and Minimum Intensity	X	X
Support retrieve and review HD raster scan patterns provided by Cirrus HD-OCT devices	X	X
Support the same intended population of trained healthcare professionals in the detection, monitoring, and management of ocular diseases	X	X
Support being purchased independently from FORUM PACS system	X	X

Table 2. Technological Comparison Summary Retina Workplace (version 2.5 – K182318) to CIRRUS HD-OCT Version 8.0 – K150977)

Description	Predicate	Subject
Allows the user to perform an en face analysis with Minimum Intensity preset	N/A	X
Allow to register images generated by Fundus photography to en face OCT fundus images or LSLO fundus images generated by CIRRUS HD-OCT devices	N/A	X
Allow to register LSLO fundus image to LSLO fundus images generated by CIRRUS HD-OCT devices	N/A	X
Provide the same functionality for processing optical coherence tomography (OCT) exam results from CIRRUS HD-OCT	X	X
Support display of these exams results in relation to reference data	X	X
Support using the same algorithms and databases to	X	X

perform ILM-RPE thickness and volume evaluations for macular thickness and macular change analyses as well as the generation of ETDRS grids		
Support automatic registration to compensate for the differences in scan location during acquisition	X	X
Support use of same algorithms to perform en face analysis with presets: VRI, Mid-Retina, IS/OS Ellipsoid, Choroid	X	X
Support use of same algorithms to perform Advanced RPE Analysis	X	X
Support use of the same algorithm to display the CIRRUS OCT-Angiography exams and – en face visualizations	X	X
Support measurements on fundus images and B-scans	X	X
Support use of the same algorithm to perform the en face OCT fundus images to en face OCT fundus image registration	X	X

Table 3. Technological Comparison Summary Retina Workplace (version 2.5 – K182318) to CIRRUS photo (K133217)

Description	Predicate	Subject
Provide the same functionality for processing optical coherence tomography exam results from CIRRUS photo	X	X
Support display of exam results in relation to reference data	X	X
Support use of same algorithms and databases to perform ILM-RPE thickness and volume evaluation for macular thickness and macular change analyses as well as the generation of ETDRS grids	X	X
Support automatic registration to compensate for the differences in scan location during acquisition	X	X
Registration of images generated by Fundus photography to OCT fundus images	X	X
Registration of HD raster scan pattern with fundus images	X	X
Support measurements on fundus images and B-scans	X	X

Table 4. Technological Comparison Summary Retina Workplace (version 2.5 – K182318) to FORUM (K122938)

Description	Predicate	Subject
Allow the user review CIRRUS HD-OCT and CIRRUS Photo OCT exam data and perform macular thickness analysis, macular changes analysis, en face analysis, and advanced RPE analysis	N/A	X
Support CIRRUS OCT-Angiography	N/A	X
Enable user to access and display results of CIRRUS HD-OCT (K150977), CIRRUS photo (K133217) stored in a DICOM archive	X	X

Support display and access fundus images stored in a DICOM archive	X	X
Support the same intended population of trained healthcare professionals in the detection, monitoring, and management of ocular diseases	X	X

PERFORMANCE DATA & SUMMARY OF VERIFICATION AND VALIDATION ACTIVITY (21 CFR §807.92(B)):

Software testing was conducted to establish the ability of the subject Retina Workplace (version 2.5 – K182318) to meet design and customer requirements.

Verification and validation activities for the Retina Workplace were conducted and the device software was found to perform as intended. The system verification test report provides the test cases, expected results for each test case and the actual results obtained. Validation testing was conducted to ensure that the device meets the customer's requirements with respect to performance.

All criteria for the verification and validation testing were met; the results demonstrate that the Retina Workplace meets all performance specifications and requirements.

SUBSTANTIAL EQUIVALENCE TO PREDICATES (21 CFR §807.92(B)(1)):

It is the opinion of Carl Zeiss Meditec AG that the Retina Workplace, (version 2.5 – K182318) is substantially equivalent to the primary predicate devices Retina Workplace (version 2.0) (K170638), Cirrus HD-OCT with Software Version 8 (K150977) and to the secondary predicate devices CIRRUS photo (K133217) and FORUM (K122938).

The indications for use for the Retina Workplace are similar to the indications for the predicate devices cited in this application.

A technological comparison and performance data demonstrate that the Retina Workplace (version 2.5 – K182318) is functionally equivalent to the predicate devices, Retina Workplace (version 2.0), Cirrus HD-OCT with Software Version 8 (K150977), CIRRUS photo (K133217), and FORUM (K122938). The differences between the proposed device, the Retina Workplace (version 2.5 – K182318), and the predicate devices are insignificant and do not raise new issues of safety or effectiveness of the device.

The verification and validation activities used to evaluate the Retina Workplace (version 2.5 – K182318), as well as the information and reports provided in this 510(k) submission, do not raise any new issues of safety or effectiveness. Retina Workplace v2.5 performs as well as the predicate devices. Therefore, it is Zeiss's opinion that the safety and effectiveness of the Retina Workplace, (version 2.5 – K182318) when used in accordance with the product labeling, is consistent with and performs as well as, the predicate devices.

510(K) SUMMARY (21 CFR §807.92(C)):

No additional concerns to safety and efficacy have been identified and based upon the comparison of technological features and the performance testing provided in Section 16, the subject Retina Workplace (version 2.5) is substantially equivalent to the predicate Retina Workplace (version 2.0), cleared under K170638.