DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 21, 2017

Carl Zeiss Meditec Ag
% Dong Hua
Sr. Regulatory Affairs Specialist
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568

Re: K170638
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
Dated: May 18, 2017
Received: May 23, 2017

Dear Dong Hua:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act);
21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kesia Alexander

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170638

Device Name
Retina Workplace

Indications for Use *(Describe)*
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.

The Retina Workplace uses CIRRUS algorithms and normative databases as quantitative tool for the comparison of macular thickness data to a database of normal subjects.

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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510(k) SUMMARY

(as per 21 CFR §807.92)

The Retina Workplace

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany +49 3641220-667 (phone) +49 3641220-282 (fax) Establishment Registration Number: 9615030
Contact Person:	Dong Hua Sr. Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 (925) 557-4204 Phone (925) 216-2184 Mobile (925) 557-4259 Fax E-mail: dong.hua@zeiss.com
Date prepared:	June 14th, 2017
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 (Release 2.0)

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 and Clearances	Clearance Date	Substantially Equivalent To:	Company
The Retina Workplace is a clinically focused workplace for retina disorders and is accessory to the FORUM PACs and is a client of the FORUM server	K150467 / May 21, 2015	The Retina Workplace is a clinically focused workplace for retina disorders and is accessory to the FORUM PACs and is a client of the FORUM server.	Carl Zeiss Meditec AG
FORUM® is a server based PACs workplace supporting generic post-processing tools (display, pan, zoom, generating reports, etc.) and interfaces with DICOM based ophthalmic devices.	K122938 / November 2, 2012	The Retina Workplace accessory client for the FORUM® PACs system providing clinically focused applications.	Carl Zeiss Meditec AG
CIRRUS™ HD-OCT containing algorithms for the detection and analysis of ophthalmic anatomy, including Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases	K150977 / September 1, 2015	The Retina Workplace as a clinically focused accessory to the FORUM® PACs workplace containing algorithms and databases for the analysis of ocular diseases including macular edema, and degeneration and other retinopathies.	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	The Retina Workplace as a clinically focused accessory to the FORUM® PACs workplace imports OCT data and Fundus images for display, storage, and report generation.	Carl Zeiss Meditec AG

INTENDED USE (21 CFR §807.92(a)(5))

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

The Retina Workplace is a software application to a Class II medical device regulated under 21 CFR §892.2050 and therefore is a Class II medical device. As a software application of the FORUM PACs system (server), the Retina Workplace client is designed to process and display CIRRUS™ HD optical coherence tomography (OCT) data and images provided by Fundus photography.

More specifically, the Retina Workplace processes the retrieved OCT exam data from CIRRUS HD-OCT and CIRRUS Photo images from the FORUM server to display the results of macular thickness analysis (MTA), macular change analysis (MCA), en face Analyses with predefined pre-sets, Advanced RPE Analysis, and raster scans (5 Line, HD 5 Line, 1 Line, HD 1 Line (100x), HD 21 Line, HD Cross, and HD Radial).

The MTA results may be compared against an age-matched population of normal subjects. Analysis and databases comparison is performed by using algorithms and normative databases previously cleared in CIRRUS HD-OCT (K150977) and CIRRUS Photo (K133217) predicate devices. The reports generated by the Retina Workplace can be displayed, printed, and the patient record can be stored back on the FORUM server database.

The Advanced RPE Analysis allows the user to examine the status of the RPE in greater detail than the Macular Thickness Analysis. In particular, Retina Workplace provides two algorithms, one to identify and measure areas of sub-RPE illumination where the OCT is able to penetrate through to the choroid, indicating that the RPE is atrophic (often associated with geographic atrophy), and one to identify and measure elevations in the RPE (often associated with drusen)."

Retina Workplace can automatically register images generated by Fundus photography with other Fundus images e.g. the en face OCT Fundus image when provided in a valid DICOM format and available in the FORUM Archive.

The fundus to fundus registration is part of the predicate devices Cirrus photo (K133217), albeit the function on the predicate device is limited to register image by Fundus photography with en face OCT Fundus images. Retina Workplace version 2.0 extended this functionality to handle LSLO Fundus image. Specifically, to register Fundus image to LSLO Fundus image and LSLO Fundus image to LSLO Fundus image. This registration functionality is used to align HD raster scan pattern to Fundus images, an equivalent function is part of the predicate device CIRRUS photo (K133217). For all performed registrations, the user has the option to register the fundus images manually.

The automatic/manual Fovea registration features (Fovea Finder™ and AutoCenter™) are currently cleared on the CIRRUS™ HD-OCT system (K150977) and CIRRUS™ Photo (K133217) devices and are also included in the Retina Workplace, since version 1.0 (K150467).

The Retina Workplace provides the same overlays as included in the currently cleared CIRRUS HD-OCT system such as:

Introduced with the Retina Workplace Release 2.0

- En face analyses overlays, with different pre-sets based on the mean / average optical reflectivity values
- Advanced RPE Analysis overlays with illumination and elevation map
- Fundus images overlaid with raster scan pattern

Introduced with the previous release of Retina Workplace (Release 1.0, K150467)

- Fundus image overlay with another Fundus image. (Fundus to Fundus registration)
- Macular thickness (ILM-RPE) overlay on the Fundus image. (Inner limiting membrane / retinal pigment epithelium)
- Macular change overlay
- ETDRS overlay on the Fundus image. (Early Treatment of Diabetic Retinopathy Study)

Overlays of Retina Workplace not provided by CIRRUS OCT devices:

- MTA thickness map overlaid with raster scan pattern
- En face analysis overlay with pre-set to create an en face image based on the minimum optical reflectivity values

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 Retina Workplace is designed in conjunction with the FORUM PACS system is to 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 substantially equivalent to the predicate devices with regard to the indications for use statement and is functionally equivalent to the predicate devices as follows:

- The Retina Workplace, Release 2.0 and the PRIMARY predicate device Retina Workplace, Release 1.0 (K150467), are clients of the FORUM PACS system and equivalent in design as they are clinically focused workplaces for retina disorders, which support the work flow of optometric and ophthalmic clinicians and their staff. Both workplaces can display retrieved OCT exams from CIRRUS OCT devices to be analyzed and reviewed

- The Retina Workplace and the SECONDARY predicate device, Cirrus HD-OCT with Software Version 8 (K150977) process OCT exam results. Macular thickness analysis results may be displayed in relation to a normative database specific to originating CIRRUS devices.

- The Retina Workplace and the SECONDARY predicate device, CIRRUS Photo (K133217), process OCT exam results. Macular thickness analysis results may be displayed in relation to a normative database specific to originating CIRRUS devices.

- The Retina Workplace and the SECONDARY predicate device, FORUM (K122938), supports the generation of reports which contain the results from optical coherence tomography data and Fundus photography and a variety of overlays.

- The Retina Workplace and the FORUM (K122938) are software devices, whereas the predicate devices, CIRRUS HD-OCT (K150977) and CIRRUS Photo (K133217) are ophthalmic devices which have both software and hardware functionalities. The primary software functionalities to support clinically focused analysis of the retina in the predicate devices are implemented in the Retina Workplace.

Note: The release 2.0 of Retina Workplace supports the currently cleared macular thickness analysis (MTA), macular change analysis (MCA), en face analysis, Advanced RPE Analysis, and raster scan algorithms from the CIRRUS HD-OCT system. MTA

results may be compared against a normative database of age-matched population of normal subjects which has also been previously cleared in the CIRRUS HD-OCT system (K150977) and the CIRRUS Photo (K133217) devices. Additionally, the MTA, MCA, and 5 line raster analysis software applications and normative databases remain unchanged from the currently cleared version of Retina Workplace (K150467), Release 1.0.

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

Bench Testing (21 CFR §807.92(b) (1))

Performance testing, in the form of software bench testing, was conducted on the Retina Workplace in the form of Unit, System Integration, and System testing against the documented product requirements. Verification and validation testing was performed to evaluate the performance and functionality of the software and the device has been found to perform as intended. Each function and/or feature was tested by means of an appropriate test case for the test specification. The verification testing demonstrates that the device performance complies with specifications and requirements identified for the Retina Workplace.

The software verification activities were divided into three phases:

- Tests accompanying development (including code inspections)
- Module and integration test phase – stabilization phase
- System verification

As part of the verification testing, in a direct comparison test, the original OCT test reports generated on the CIRRUS HD-OCT and CIRRUS photo were compared to the reports generated by the Retina Workplace using the same test data, to verify that the results contained in both reports were equivalent.

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plan.

Testing Environment:

The client and server operating systems were also evaluated during verification. The results determined that client, Retina Workplace, is suitable for the same operating systems for which the respective server, FORUM, is released and that it is suitable under the following operating systems:

Operating Systems (server):

- Windows 7 (64 bit) with Service Pack 1 or
- Windows 8.1 (64 bit) or
- Windows Server 2008 R2 (64 bit) with Service Pack 1
- Windows Server 2012 R2
- Windows 10 (64 bit)

Operating Systems (client):

- OS X 10.10 (Yosemite)
- OS X 10.11 (El Capitan)
- Windows Server 2008 R2 (64 bit)
- Windows Server 2012 R2 (64 bit)
- Windows 7 (64 bit)
- Windows 7 (32 bit)
- Windows 8.1 (64 bit)
- Windows 10 (64 bit)

Non-Clinical Validation Test Results (21 CFR §807.92(b) (2))

Validation of clinical functionalities (Use Case) was completed by ophthalmologists using a production equivalent Retina Workplace system with verified software including representative data (sample data that is representative of clinical cases) installed on a segregated computer and used as a non-clinical system. The validation participants used the Retina Workplace system, executed test cases that simulated the use of the device in a clinical environment and completed questionnaires rating the various aspects of the software.

Verification and validation activities met their acceptance criteria successfully and proved that the product, the Retina Workplace, meets its requirements and intended uses.

Testing to Consensus Standards (21 CFR §807.92(b)(1))

The Retina Workplace has been tested to meet the requirements for conformity (where applicable) to multiple industry standards. The R&D evaluation of the relevant testing to consensus standards is documented. The Retina Workplace, is an accessory application to the FORUM PACS system.

The Retina Workplace is DICOM compliant according to the DICOM compliance statement as provided on the Carl Zeiss internet site: www.zeiss.com/dicom

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

As previously indicated, the Retina Workplace has been tested to meet the product requirements (PRS) and software requirements (SRS) and is considered to be substantially equivalent to the Primary predicate device and secondary predicate devices as indicated above.

510(K) SUMMARY (21 CFR §807.92(C)):

In summary, based on the successful verification and validation testing to the software acceptance criteria, it is ZEISS' opinion that the Retina Workplace client, as an accessory to the FORUM PACs system (K122938), does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

Additionally, all testing deemed necessary was conducted on the Retina Workplace to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate devices.