



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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May 21, 2015

Carl Zeiss Meditec, Inc.  
% Ms. Christine Dunbar  
Manager, Regulatory Submission  
5160 Hacienda Drive  
Dublin, CA 94568

Re: K150467  
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: February 18, 2015  
Received: February 23, 2015

Dear Ms. Dunbar:

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 yours,

**Kesia Y. Alexander -A**

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

## Indications for Use

510(k) Number (if known)

K150467

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.

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## 510(K) SUMMARY

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### 5. 510(K) SUMMARY

#### 510(k) SUMMARY ( as per 21 CFR §807.92)

#### The Retina Workplace

#### GENERAL INFORMATION

Manufacturer: Carl Zeiss Meditec AG  
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Date prepared: February 18, 2015

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

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**510(K) SUMMARY**

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
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	K111157 / January 19, 2012	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.	K112184 / June 18, 2012	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
FORUM® Glaucoma Workplace As a clinically focused accessory to the FORUM	K141297 / October 3, 2014	The Retina Workplace as a clinically focused accessory to the FORUM® PACs	Carl Zeiss Meditec AG

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Predicate Devices and Clearances	Clearance Date	Substantially Equivalent To:	Company
PACs and is a client of the FORUM server	Reference Predicate	workplace and is a client of the FORUM server.	

### 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 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.

### 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), and 5 line raster analysis. The 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 (K111157) and CIRRUS Photo (K112184) predicate devices. The reports generated by the Retina

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## **510(K) SUMMARY**

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Workplace can be displayed, printed, and the patient record can be stored back on the FORUM server database.

In addition, Retina Workplace can automatically register images generated by Fundus photography with the OCT cube image when provided in a valid DICOM format, including the necessary pixel spacing. Additionally, the user has the option to register the fundus / OCT images manually. The automatic/manual image registration features (Fovea Finder™ and AutoCenter™) are currently cleared on the CIRRUS™ HD-OCT system (K111157) and CIRRUS™ Photo (K112184) devices.

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

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

### **RISK MANAGEMENT AND GENERAL SAFETY AND EFFECTIVENESS**

The device labeling contains instructions for use and any necessary cautions and warnings, 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.

Refer to Sections 16 and 21 for the Risk Management documentation.

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

The Substantial Equivalence comparison chart (Section 12) demonstrates the comparison of the technological characteristics of the Retina Workplace to the currently cleared predicate devices. The reference predicate, FORUM Glaucoma Workplace is the first clinically focused client accessory to the FORUM PACS server. The design of the FORUM PACS server 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:

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- The Retina Workplace and the 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 predicate device FORUM (K122938) are software devices, whereas the predicate devices, CIRRUS HD-OCT (K111157) and CIRRUS Photo (K112184) 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.
- The Retina Workplace and the predicate devices, CIRRUS HD-OCT [with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157)] and CIRRUS photo (K112184), process OCT exam results and display these results in relation to a normative database.

Note: The Retina Workplace, Release 1, supports the currently cleared macular thickness analysis (MTA), macular change analysis (MCA), and 5 line raster analysis only. The results may be compared against an age-matched normative population database of normal subjects which has been previously cleared in the CIRRUS HD-OCT system (K111157) and the CIRRUS Photo (K112184) devices. The MTA, MCA, and 5 line raster analysis software applications and normative databases remain unchanged from the currently cleared versions in the CIRRUS HD-OCT and CIRRUS Photo products.

- The Retina Workplace and the reference FORUM Glaucoma Workplace (K141297) are similar workplaces in design as they are both clients of the FORUM server, each a clinically focused workplace to support the work flow of the optometric and ophthalmic clinicians and their staff.

### **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.

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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, the 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):

- Microsoft Windows 7 (64 bit) with Service Pack 1
- Microsoft Windows 8 (64 bit)
- Microsoft Windows Server 2008 R2 with Service Pack 1

Operating Systems (client):

- Windows XP (32 bit) with Service Pack 3
- Windows 7 (32 or 64 bit) with Service Pack 1
- Windows 8 (64 Bit)
- Windows Server 2008 R2 with Service Pack 1
- Windows Server 2008 (TS) R2 (64 bit) with Service Pack 1
- OS X 10.8 (Mountain Lion)

### 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

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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 Workplace.

The Retina Workplace is DICOM compliant according to the FORUM DICOM compliance statement, Doc ID: LEH-CS-044, Rev. 3.3.

Refer to Section 9 for this documentation.

### **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 predicate and reference 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 server system, does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate and reference 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 and reference devices.