Carl Zeiss Meditec AG
% Maria Golovina
Head of Regulatory - USA
Carl Zeiss Meditec USA Inc
5300 Central Parkway
Dublin, California 94548

Re: K213527
Trade/Device Name: Forum
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: NFJ
Dated: June 30, 2022
Received: July 6, 2022

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/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,

for 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)*
K213527

Device Name
FORUM

Indications for Use *(Describe)*
FORUM is a software system intended for use in management, processing of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications (including but not limited to Retina Workplace, Glaucoma Workplace).

FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.

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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FORUM: 510(k) Summary

In accordance with 21 CFR 807.92, the following summary of information is provided in the 510(k) submission.

1. Identification of the Submitter

Applicant	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany
Primary Contact	Maria Golovina Head of Regulatory Affairs - USA Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (925) 216-1078 Phone | (925) 557-4259 Fax E-mail: maria.golovina@zeiss.com (preferred)
Secondary Contact	Tanesha Bland Senior Regulatory Affairs Specialist- USA Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (925) 216-7963 Phone E-mail: tanesha.bland@zeiss.com (preferred)
Date Prepared	August 11, 2022

2. Identification of the Product

Trade Name	FORUM
Software Version	Software Version 4.3
Classification/Common Name	System, Image Management, Ophthalmic
Device Class	II
Product Code	NFJ

3. Predicate Device to which Equivalence is Claimed

Primary Predicate:

Device Name	FORUM Archive and Viewer
Manufacturer	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany
510(k) Number	K122938
Product Code	NFJ
Classification	System, Image Management, Ophthalmic

4. Summary of Device Description

FORUM and its accessories are a computer software system designed for management, processing, and display of patient diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications.

FORUM receives data via DICOM protocol from a variety of ophthalmic diagnostic instruments (such as CIRRUS, CLARUS, and 3rd Party systems), allows central data storage and remote access to patient data. This version of FORUM allows the user to access their data in the cloud via ZEISS developed non-medical device accessories. FORUM is an ophthalmic data management solution. FORUM provides basic viewing functionalities and is able to connect all DICOM compliant instruments.

This version of FORUM provides additional device functions such as review and annotation functionality of fundus images/movies, display of OCT image stacks, bidirectional data exchange between FORUM Workplaces, customization of document viewing abilities, user interface improvements, and user management updates.

This version of FORUM has additional non-medical device functions that are performed by non-medical device accessories, such as documentation storage, export of data in various formats, export to the cloud, improved IT integration capability into the existing IT network, image sorting, EMR log in improvements, numerous backend improvements with the purpose of streamlining clinical workflow.

5. Intended Use and Indications for Use

The Indications for Use (IFU) statement for the subject device is as follows:

FORUM is a software system intended for use in management, processing of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications (including but not limited to Retina Workplace, Glaucoma Workplace).

FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.

Prescription Use (Rx)

6. Substantial Equivalence Comparison to the Predicate Device

The substantial equivalence was drawn solely on the medical device features as they were related to the predicate.

Table 1. Subject Device to Reference Device Comparison (Technical Characteristics)

Attribute/Function	Subject Device (K213527)	Primary Predicate Device (K122938)	Equivalency Analysis
Trade Name	FORUM	FORUM Archive and Viewer	Updated
Software version	Software version 4.3	Software version 3.0	Updated
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	Identical
Device Classification Name	System, Image Management, Ophthalmic	System, Image Management, Ophthalmic	Identical
Regulation Description	Medical image management and processing system	Picture archiving and communications system	Equivalent. Regulation change.
Regulation medical specialty	Ophthalmic	Ophthalmic	Identical
Review panel	Ophthalmic	Ophthalmic	Identical
Product code, subsequent product codes	NFJ – Class II	NFJ – Class II	Identical
Regulation number	21CFR892.2050	21CFR892.2050	Identical
Device class	II	II	Identical
Indications for use	FORUM is a software system intended for use in management, processing of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications (including but not limited to Retina Workplace, Glaucoma Workplace).	FORUM is a software system intended for use in management, processing of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications.	Equivalent. A removal of the word 'storage' and display from the indications for use due to an updated definition of MIMS does not constitute a substantial change, thus is deemed equivalent.

Attribute/Function	Subject Device (K213527)	Primary Predicate Device (K122938)	Equivalency Analysis
	FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.	FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.	
Application	Ophthalmology	Ophthalmology	Identical
Platform/Operating System	Server: • Windows Server 2012 R2, • Windows Server 2016, • Windows Server 2019, • Windows 8.1, • Windows 10	Server: • Windows XP (32 bit) with Service Pack 3 • Windows Server 2003 (32 bit) with Service Pack 2 • Windows 7 (64 bit) with Service Pack 1 Windows Server 2008 R2 (64 bit) with Service Pack 1	Equivalent; backend improvements do not impact the indications for use, device risk profile, and technical specifications of the subject device as demonstrated in risk documentation and testing results.
	Client: • Windows Server 2012 R2, • Windows Server 2016, • Windows Server 2019, • Windows 8.1, • Windows 10 • Apple OS X 11.x (BigSur)	Client: • Windows XP (32 bit) with Service Pack 3Windows 7 (64 bit) with Service Pack 1 • Windows Server 2008 R2 (64 bit, English Edition) • Apple OS 10.7 “Lion”	Equivalent; backend improvements do not impact the indications for use, device risk profile, and technical specifications of the subject device as demonstrated in risk documentation and testing results.
Database Features*	Central database: **Yes**	Central database: **Yes**	Identical
	Administer patient data: **Yes**	Administer patient data: **Yes**	Identical
	Patient chart/ patient management: **Yes**	Patient chart/ patient management: **Yes**	Identical
	Search & sort patients/documents: **Yes**	Search & sort patients/documents: **Yes**	Identical

Attribute/Function	Subject Device (K213527)	Primary Predicate Device (K122938)	Equivalency Analysis
	Administer exam data: **Yes**	Store & administer exam data: **Yes**	Identical
	Search Exams: **Yes**	Search Exams: **Yes**	Identical
	Scheduling exams: **Yes** – Modality Worklist Scheduler (Patient to Device)	Scheduling exams: **Yes** – Modality Worklist Scheduler (Patient to Device)	Identical
Image Processing	Image Processing Function (Review of medical documents) – Fundus: **Yes** – Stereo view for fundus images, red green blue (RGB) split for fundus images, display of fundus angiography movies, rotation of fundus images, measurements on wide-field fundus images	Image Processing Function (Review of medical documents) - Fundus: - **Yes**, to general functionality - **No**, to specific functions as compared to the subject device	Different; however, the addition of this functionality does not impact the indications for use, device risk profile, and technical specifications of the subject device as demonstrated in risk documentation and testing results.
	Image Processing Function (Review of medical documents) Image Annotations: **Yes**, Addition of free hand and circle measurement ability, text annotations on images, rotation	Image Processing Function (Review of medical documents) Image Annotations: - **Yes**, to general functionality - **No**, to specific functions as compared to the subject device	Different; however, the addition of this functionality does not impact the indications for use, device risk profile, and technical specifications of the subject device as demonstrated in risk documentation and testing results.
Access/Connectivity*	Connection to LAN: **Yes**	Connection to LAN: **Yes**	Identical
	DICOM Interface: **Yes**	DICOM Interface: **Yes**	Identical
	Remote data access via Internet: **No, only via Virtual Private Network**	Remote data access via Internet: **No, only via Virtual Private Network**	Identical
	Import exam data from various ophthalmic diagnostic devices: **Yes**	Import exam data from various ophthalmic diagnostic devices: **Yes**	Identical

Attribute/Function	Subject Device (K213527)	Primary Predicate Device (K122938)	Equivalency Analysis
	Interface to Electronic Medical Records (EMRs) or Practice Management Systems: **Yes**	Interface to Electronic Medical Records (EMRs) or Practice Management Systems: **Yes**	Identical
	Cloud Connection: **Yes via ZEISS developed non-medical device accessories**	Cloud Connection: **No**	Equivalent. The addition of the non-medical accessories that support cloud connectivity does not impact the indications for use and do not impact the functionality of the medical device.
	Data Exchange: **Yes**, bidirectional data exchange between FORUM Workplaces	Data Exchange: **Yes**, unidirectional data exchange between FORUM Workplaces	Different; however, the addition of this functionality does not impact the indications for use, device risk profile, and technical specifications of the subject device as demonstrated in risk documentation and testing results.
Image/Data Transfer via DICOM	Yes	Yes	Identical

*The addition of new and/or modified medical device functions does not impact safety and equivalence of the subject device because risks associated with these functions were mitigated. Appropriate risk analysis and testing documentation was provided to demonstrate that these modifications do not impact the substantial equivalence as compared to the predicate device.

**The addition of new and/or modified non-medical functions and accessories does not impact safety and equivalence of the subject device because the functionality they provide does not have an impact to the FORUM medical device. This was demonstrated by providing appropriate risk assessments and testing information.

7. Summary of the Studies

FORUM (version 4.3) has successfully undergone extensive software verification and validation testing to ensure that all requirements for proposed changes have been met. 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 indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

All testing followed internally approved procedures and processes. These procedures and processes are in compliance with referenced standards and FDA guidance documents.

8. Conclusion

The indications for use are equivalent to the indications for use of the predicate device; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

The technological characteristics and risk profile of the subject device are equivalent to the predicate device and reference device; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

Testing methods are equivalent to those of the predicate device and reference device; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

Therefore, the subject device meets the requirements for substantial equivalence.