March 8, 2024

Carl Zeiss Meditec AG
% Aditya Rao
Regulatory Affairs Specialist - USA
Carl Zeiss Meditec, Inc
5300 Central Parkway
Dublin, California 94568

Re: K233421
Trade/Device Name: Rescan 700 (SW 3.0)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: January 29, 2024
Received: January 30, 2024

Dear Aditya Rao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Y. Ng -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K233421

Device Name

RESCAN 700 (SW 3.0)

Indications for Use *(Describe)*

RESCAN 700 provides non-contact, high resolution, optical coherence tomographic (OCT) and biomicroscopic imaging of the anterior and posterior segment of the eye via an ophthalmic surgical microscope. The RESCAN 700 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, macula, and optic disc, as well as imaging of anterior ocular structures, including the cornea, lens and anterior chamber angle.

RESCAN 700 uses the assistance system (CALLISTO eye) that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The assistance system allows the remote control of RESCAN 700.

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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In accordance with 21 CFR 807.92 the 510(k) Summary for the RESCAN 700 is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena Germany
Applicant Contact	Dr. Katrin Faber Head of RA/CA SPS +49 7364 20 1606 Phone | E-mail: katrin.faber@zeiss.com
Primary Correspondent	Aditya Rao Regulatory Affairs Specialist - USA Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (925) 549-9579 Phone | (925) 557-4259 Fax E-mail: aditya.rao@zeiss.com (preferred)
Date Prepared:	March 08, 2024

2. DEVICE

Device Trade Name:	RESCAN 700 (SW 3.0)
510(k) Number:	K233421
Classification:	21CFR886.1570 Tomography, Optical coherence
Regulatory Class:	II
Product Code:	OBO

3. PREDICATE DEVICE

Predicate Device:	RESCAN 700 (Software Version 2.0)
510(k) number	K180229
Classification:	21CFR886.1570 Tomography, Optical coherence
Regulatory Class:	II
Product Code:	OBO

4. DEVICE DESCRIPTION

RESCAN 700 brings Spectral Domain OCT technology to the ZEISS ophthalmic surgical microscopes (e.g. ARTEVO 800). Used in conjunction with the assistance system, CALLISTO eye, OCT images taken intra-operatively are presented on the monitor and may also be seen within the surgeon's oculars using the surgical microscopes integrated data injection system (IDIS). OCT images may be stored for subsequent retrieval using CALLISTO eye's data management system. RESCAN 700 can be controlled via the touch panel of the assistance system or via the foot control panel of an ophthalmic surgical microscope

5. INDICATIONS FOR USE

RESCAN 700 provides non-contact, high resolution, optical coherence tomographic (OCT) and biomicroscopic imaging of the anterior and posterior segment of the eye via an ophthalmic surgical microscope. The RESCAN 700 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, macula, and optic disc, as well as imaging of anterior ocular structures, including the cornea, lens and anterior chamber angle.

RESCAN 700 uses the assistance system (CALLISTO eye) that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The assistance system allows the remote control of RESCAN 700.

This device is for Prescription Use (Rx) only.

6. SUBSTANTIAL EQUIVALENCE

6.1. Primary Predicate

Table 1. Subject to Predicate Device Comparison Table – Indications for Use

Subject Device (K233421)	Predicate Device (K180229)	Equivalency Analysis
RESCAN 700 provides non-contact, high resolution, optical coherence tomographic (OCT) and biomicroscopic imaging of the anterior and posterior segment of the eye via an ophthalmic surgical microscope. The RESCAN 700 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, macula, and optic disc, as well as imaging of anterior ocular structures, including the cornea, lens and anterior chamber angle. RESCAN 700 uses the assistance system (CALLISTO eye) that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The assistance system allows the remote control of RESCAN 700	RESCAN 700 provides non-contact, high resolution, optical coherence tomographic (OCT) and biomicroscopic imaging of the anterior and posterior segment of the eye via an ophthalmic surgical microscope. The RESCAN 700 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, macula, and optic disc, as well as imaging of anterior ocular structures, including the cornea, lens and anterior chamber angle. RESCAN 700 uses the assistance system (CALLISTO eye) that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The assistance system allows the remote control of RESCAN 700	Identical

Table 2. Subject to Predicate Device Comparison Table – Technical Characteristics

Attribute	Subject Device (K422421)	Primary Predicate Device (K180229)	Equivalency Analysis
Device name	RESCAN 700 (SW 3.0)	RESCAN 700 (SW2.0)	N/A
Software Version	3.0	2.0	N/A
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	Identical
510(k)	TBD	**K180229**	N/A
Classification Product Code	OBO	OBO	Identical
Regulation #	21CFR886.1570 Tomography, Optical Coherence	21CFR886.1570 Tomography, Optical Coherence	Identical
Review Panel	Ophthalmic	Ophthalmic	Identical
Patient Contact	No	No	Identical
OCT methodology	Spectral Domain OCT	Spectral Domain OCT	Identical

Attribute	Subject Device (K422421)	Primary Predicate Device (K180229)	Equivalency Analysis
Optical source	Super Luminescent Diode (SLD)	Super Luminescent Diode (SLD)	Identical
Wavelength	840 nm	840 nm	Identical
Bandwith	3 dB: 32 nm	3 dB: 32 nm	Identical
Radiation power	< 4 mW	< 4 mW	Identical
Emission duration	> 16 min	> 16 min	Identical
Beam divergence	Colliminated beam	Colliminated beam	Identical
Optical power	620 µW on cornea	620 µW on cornea	Identical
OCT Scan Speed	27,000 A-Scans per second	27,000 A-Scans per second	Identical
OCT Scan Area	Scan area, after OCT telescope, max. 38 x 36° x 38 x 36°	Scan area, after OCT telescope, max. 38 x 36° x 38 x 36°	Identical
OCT Scan Dimensions (Posterior Segment)	16 x16 mm (Cube scans) 3 to 16 mm for line scans (in steps of 1 mm)	16 x16 mm (Cube scans) 3 to 16 mm for line scans (in steps of 1 mm)	Identical
A-Scan depth	2.9 mm (in the tissue) 5.8 mm (in the tissue)	2.9 mm (in the tissue) 5.8 mm (in the tissue)	Identical
Axial Resolution	5.5 µm (in the tissue) at 2.9 mm scan depth 11.0 µm (in the tissue) at 5.8mm scan depth	5.5 µm (in the tissue) at 2.9 mm scan depth 11.0 µm (in the tissue) at 5.8mm scan depth	Identical
Signal to noise ratio	>=26 dB	>=26 dB	Identical
Sensitivity noise level	<10 dB	<10 dB	Identical
Camera Resolution	2048 pixel * 200 microns	2048 pixel * 20 microns	Equivalent The pixel width of 200 microns compared to 20 microns does not impact the axial resolution or signal quality
Traversal Resolution (OCT Scan)	15 µm (in the tissue)	15 µm (in the tissue)	Identical
Scan rotation	Adjustable 0 – 360° (step with 1°)	Adjustable 0 – 360° (step with 1°)	Identical
Scan Patterns (OCT Scan)	Single line, cross hair, 5-line scan, cube scan	Single line, cross hair, 5-line scan, cube scan	Identical
Scan Types	Live / Capture	Live / Capture	Identical for RESCAN 700.

Abbreviation: HD: High Definition SD: Standard	HD 1 Line SD 1 Line HD 5 Line SD 5 Line HD 2 Line SD 2 Line (Note: The 2 Line scan = Middle Vertical & Middle Horizontal B-scans)	HD 1 Line SD 1 Line HD 5 Line SD 5 Line Cube Scan 200x200 Cube Scan 512x128	HD 1 Line SD 1 Line HD 5 Line SD 5 Line HD 2 Line SD 2 Line (Note: The 2 Line scan = Middle Vertical & Middle Horizontal B-scans)	HD 1 Line SD 1 Line HD 5 Line SD 5 Line Cube Scan 200x200 Cube Scan 512x128	IFU reflects Scan Mode that can be used within the whole system
Refresh rate	5 Hz for each line in scan type		5 Hz for each line in scan type		Identical
OCT focus	Adjustable independent		Adjustable independent		Identical

Attribute	**Subject Device (K422421)**	**Primary Predicate Device (K180229)**	**Equivalency Analysis**
	of the microscope focus	of the microscope focus	
OCT Scan Pixels	1024 axial, 200 – 4096 transverse	1024 axial, 200 – 4096 transverse	Identical
Measurement of ocular structures	No	No	Identical
Normative Databases	No	No	Identical
Configuration	OCT System (Box and OCT Scanning Unit) integrated into a surgical Microscope (e.g. ARTEVO 750/850). Connected to assistance system, CALLISTO eye, for display of images on monitor and integrated touchscreen with PC.	OCT System (Box and OCT Scanning Unit) integrated into a surgical Microscope (e.g. ARTEVO 800). Connected to assistance system, CALLISTO eye, for display of images on monitor and integrated touchscreen with PC.	Identical
Surgical Microscopes+Software	ARTEVO 750/850 CALLISTO eye 5.0 (K232944)	OPMI LUMERA 700 or ARTEVO 800 CALLISTO eye 3.6 (K180858)/ CALLISTO eye 3.7 (K231676)	**Equivalent**. (Connectivity to OPMI LUMERA 700 / ARTEVO 800 and previous CALLISTO eye versions is no longer supported in RESCAN700 SW3.0
Materials – Patients Contacting	None	None	Identical

Electrical Requirements	Supplied by surgical microscope: (115): 100 - 125 VAC, 50-60 Hz (230): 220 - 240 VAC, 50-60Hz Power consumption: Max. 1200 VA	Supplied by surgical microscope: (115): 100 - 125 VAC, 50-60 Hz (230): 220 - 240 VAC, 50-60Hz Power consumption: Max. 1200 VA	Identical
Electrical Safety Parameters	Enclosure Protection: IP20 Protection Class: 1 Device Type (IEC 60601-1): no applied part	Enclosure Protection: IP20 Protection Class: 1 Device Type (IEC 60601-1): no applied part	Identical
Ambient conditions for storage and transport	Temp. -20° to +60° C Relative Humidity 10% to 90% (without condensation) Atmospheric Pressure 500 to 1060 hPa	Temp. -20° to +60° C Relative Humidity 10% to 90% (without condensation) Atmospheric Pressure 500 to 1060 hPa	Identical
Ambient conditions for operation	Temp. +10 °C to +40 °C Relative Humidity 30 % to 75 % (excluding condensation) 700 to 1060 hPa Altitude up to 3,000m above sea level	Temp. +10 °C to +40 °C Relative Humidity 30 % to 75 % (excluding condensation) 700 to 1060 hPa Altitude up to 3,000m above sea level	Identical for RESCAN 700. IFU reflects ambient conditions for the whole system.

The proposed product, RESCAN 700, will be used with CALLISTO eye, Software version 5.0 (K232944). The predicate device, RESCAN 700, was used with CALLISTO eye Software version 3.6 (K180858) & CALLISTO eye Software version 3.7 (K231676).

7. SUMMARY OF STUDIES

Non-Clinical Performance Testing

Software Verification and Validation Testing
Rescan 700 is a cyber device per 524B(c) of the Food, Drug & Cosmetic Act. ZEISS has followed the recommendations in the Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (fda.gov) (https://www.fda.gov/media/119933/download) guidance document (September 27, 2023). RESCAN 700 was tested according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (June 2023). In addition, the software testing also followed the Carl Zeiss Meditec internal software development procedure that follows the IEC 62304:2006+AC:2008 + AC:2015 – Medical device software – Software life cycle processes. Validation has been conducted according to IEC 62366. Testing passed.

Electromagnetic compatibility (EMC) and Electrical Safety Testing
Electrical safety and EMC testing were conducted in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6 standards. Testing passed.

Animal/Clinical Performance Testing

Animal and Clinical testing **was not** conducted.

8. REASONS FOR 510(k)

The subject device qualifies as a class II medical device and is therefore subject to a premarket notification.

The main purpose of this 510(k) is to bring FDA up to date on non-significant changes implemented since the last 510(k) clearance for RESCAN 700 SW 2.0 (K180229).

In summary, the changes include:

- Minor Software changes
- Changes to components and parts on the RESCAN 700 due to obsolescence reason, cost issues and minor improvements
- Minor changes to the instruction for use.

9. 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.