January 11, 2019

Carl Zeiss Meditec AG
℅ Mandy Ambrecht
Staff Regulatory Affairs Specialist
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568

Re: K180229
Trade/Device Name: RESCAN 700, CALLISTO eye
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: December 7, 2018
Received: December 10, 2018

Dear Mandy Ambrecht:

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,

Bradley S. Cunningham -S

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)*
K180229

Device Name
RESCAN 700

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.

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510(k) SUMMARY
(per 21 CFR §807.92)

RESCAN 700

GENERAL INFORMATION

Manufacturer:
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Date Summary Prepared:	January 3, 2019
Classification name	Ophthalmoscope
Classification	886.1570
Class	II
Product Code	OBO
Trade / Proprietary Name	RESCAN 700
Common Name	Tomography, Optical coherence

Primary Predicate Device

Company:	Carl Zeiss Meditec AG
Device:	RESCAN 700, K141844

Secondary Predicate Device

Company:	Carl Zeiss Meditec AG
Device:	CIRRUS photo, K112184

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

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.

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

RESCAN 700
RESCAN 700 brings Spectral Domain OCT technology to the Zeiss OPMI Lumera 700 ophthalmic surgical microscope. 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 OPMI Lumera 700's 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.

Product Update: RESCAN 700
The proposed RESCAN 700 device and its primary functionality remain unchanged from the previously cleared device while including the following modifications:

- **Improvement of OCT Visualization**

  To improve the visual appearance of the live OCT images, the standard image processing methods for noise reduction were optimized.

- **Increased Power of OCT Beam**

  The power of the OCT Beam was increased from 490 µW to 620 µW to improve the signal-to-noise ratio.

- **Increased Scan Depth**

  The scan depth was increased to provide images at a scan depth of 2.9 mm or 5.8 mm.

RESCAN 700 is used with CALLISTO eye Software version 3.6.

CALLISTO eye Software version 3.6 is an assistance, information, and documentation system to support ophthalmic surgical procedures. CALLISTO eye software operates as an adjunct to the OPMI Lumera family of ophthalmic surgical microscopes to process real-time videos and OCT data (B-Scan images). CALLISTO eye must be installed on a touchscreen Panel PC; the Panel PC is offered as an accessory.

In conjunction with RESCAN 700 the following modifications were added to CALLISTO eye Software version 3.6.

- Ability to record surgical videos directly to a connected USB hard drive.
- The OCT function was enhanced by adding OCT XY-tracking for the Scan Location Marker. The functionality is similar to the Z-tracking function but works in the XY-plane instead of the Z-axis.

Table 5-1 presents the functions offered by the previous and proposed CALLISTO eye with a focus on the interaction with RESCAN 700.

Table 5-1: CALLISTO eye Functions by Software Version
(Note: The functionality marked with an asterisk (*) is not the subject of this 510(k) Premarket Notification.)

CALLISTO eye Functions	SW Version 3.2	SW Version 3.6
as cleared in premarket notification	K141844	
Network connectivity	x	x
User management	x	x
Updated Patient management	x	x
Surgery documentation (video recording and still images)	x	x
Ophthalmic surgical microscope remote control (OPMI LUMERA 700)	x	x
Live video	x	x
Eye tracking		x
New Export of OCT data to connected PACS system (FORUM)*		x

CALLISTO eye Functions	SW Version 3.2	SW Version 3.6
as cleared in premarket notification	K141844	
Updated Control of the RESCAN 700 (OCT Camera) connected to the OPMI LUMERA 700	x	x
Visualization of optical coherence tomography (OCT) data	x	x
Capture and review of OCT data (images and B-scans)	x	x
Support of 1-Line, 2-Line (OCT cube) and 5-Line OCT data	x	x
New XY-tracking support for Scan Location Marker (for OCT views based on vessels)		x
New Support for 2.9 mm and 5.8 mm scan depths		x
New Default combination of scan length and scan depth.		x
Updated Combined full screen mode for microscope live video and OCT live view		x
New Icon-based ocular overlays to visualize the provided information (“Cockpits”) in the data injection system of the connected microscope		x
Import / Export of patient treatment data to a USB storage device	x	x
New USB recording: Surgery documentation can be recorded in parallel to a USB hard drive		x

RISK MANAGEMENT

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means, protection measures and user instructions. To confirm that the measures are effective and that the product meets its intended uses, verification of requirements and standards, and validation of the clinical workflow was performed. Carl Zeiss Meditec adheres to recognized and established industry practice and relevant international standards where indicated.

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

Performance testing was conducted on the subject device to address modifications on RESCAN 700. Existing performance testing remains valid. The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate devices to which it has been compared.

RESCAN 700 was designed and tested to the applicable standards for electrical and optical safety and verified to established standards. Testing of the device with RESCAN 700, OPMI Lumera 700 and CALLISTO eye Panel PC was conducted to demonstrate conformance to the third edition of 60601-1 in addition to the IEC 60601-1-2 standard for electromagnetic compatibility.

RESCAN 700 and CALLISTO eye conform to the applicable FDA recognized and international IEC and ISO standards with regards to performance and safety (see Table 5-2).

Table 5-2: FDA Recognized Standards

FDA Recognized Standards	
Identification	**Description**
ISO 14971: 2007	Medical Devices – Application of Risk Management to Medical Devices
ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
ISO 10936-2:2010	Optics and photonics - Operation microscopes - Part 2: Light hazard from operation microscopes used in ocular surgery
ISO 15004-2:2007	Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection

FDA Recognized Standards	
Identification	**Description**
IEC 62471:2006	Photobiological safety of lamps and lamp systems
IEC 62304:2015	Medical device software - Software life cycle processes
NEMA PS 3.1-3.20	Digital Imaging and Communications in Medicine (DICOM)

In addition to systems testing, software verification activities completed were divided into three phases:

- Tests accompanying development (including code inspections)
- Integration test phase – stabilization phase
- System verification

Verification and validation activities were successfully completed and prove that RESCAN 700 and CALLISTO eye meet their requirements and perform together as intended.

Clinical performance testing

A clinical study was conducted to compare visualization quality of relevant posterior- and anterior-segment ocular structures during ocular surgery from OCT images between two RESCAN 700 systems using different software versions at the three available scan depths (2.0 mm [predicate device], 2.9 mm, 5.8 mm). Obtained images were anonymized and graded for clinical utility in a randomized order by three independent, masked graders using a pre-specified grading scale. A total of 22 participants were enrolled (11 with corneal conditions, seven with glaucoma, four with retina conditions) and 84 images were obtained. All images were successfully assessed by all graders, with fair to good concordance between graders. Image quality was similar between the 2.0 mm and 2.9 mm scan depths in the corneal and glaucoma surgery sub-groups. Scans at the 2.9 mm scan depth were rated slightly higher than those at the 2.0 mm scan depth in the retinal surgery sub-group. Scans at 5.8 mm were rated lower than those at 2.0- and 2.9-mm scan depths in the corneal and glaucoma surgery sub-groups. In summary, the results demonstrate that OCT image quality at the new scan depth of 2.9 mm is acceptable. Images at the 5.8 mm scan depth may allow for a view of ocular structures with additional spatial context at the expense of finer detail.

TECHNOLOGICAL CHARACTERISTICS (21 CFR §807.92(a)(6)) AND SUBSTANTIAL EQUIVALENCE (21 CFR §807.92(a)(3))

It is the opinion of Carl Zeiss Meditec AG that the proposed device, RESCAN 700 is substantially equivalent to RESCAN 700 (K141844) and CIRRUS photo (K112184) with regards to indications for use. RESCAN 700 and CIRRUS photo are both intended to provide OCT images of the anterior and posterior segment of the eye. Both devices employ a non-invasive, non-contact low-coherence interferometry technique to generate cross-sectional images of internal ocular tissue microstructures by measuring optical reflections from tissue.

Both devices obtain high-resolution images using spectral domain optical coherence tomography.

Differences with the proposed device include modifications to improve visualization constituting increased OCT power that remains below the level of CIRRUS photo and increased scan depth.

The proposed product, RESCAN 700, will be used with CALLISTO eye, Software version 3.6. The predicate device, RESCAN 700, was used with CALLISTO eye Software version 3.2 (K141844). Both versions of CALLISTO eye provide non-diagnostic video documentation and image capture for ophthalmic surgeries and allow remote control of the surgical microscope.
Both products inject information such as light, zoom and recording into the right ocular; the proposed device uses “Cockpits”, icon-based ocular overlays to visualize the provided information in the data injection system of the connected microscope.

SUMMARY (21 CFR §807.92(b)(3))

RESCAN 700 has the same intended use and technological characteristics as the predicate devices, RESCAN 700 (K141844) and the same intended use as CIRRUS photo (K112184). RESCAN 700 was and continues to be used with CALLISTO eye.

The modifications to the RESCAN 700 device were implemented to improve OCT visualization while remaining compliant with the applicable standards for optical light hazards. These modifications do not raise new issues of safety or effectiveness. Therefore, ZEISS believes that the subject device, RESCAN 700 is substantially equivalent to the predicate devices, RESCAN 700 (K141844) and CIRRUS photo (K112184).