DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

Carl Zeiss Meditec, Inc.
Ms. Sarah Harrington, M.S., MBA
Staff Regulatory Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K141068
Trade/Device Name: Zeiss Cataract Suite markerless
Regulation Number: 21 CFR 886.1850
Regulation Name: Biomicroscope, Slit-Lamp, AC-powered
Regulatory Class: Class II
Product Code: HJO, NFJ, HMR, EPT, HRM
Dated: July 29, 2014
Received: July 30, 2014

Dear Ms. Harrington:

This letter corrects our substantially equivalent letter of September 9, 2014.

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" (21CFR 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 -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

1.0 INDICATIONS FOR USE – ZEISS CATARACT SUITE MARKERLESS

510(k) Number (if known):_____

Device Name(s): ZEISS Cataract Suite markerless

The ZEISS Cataract Suite markerless workflow uses a preoperative image capture tool from the IOLMaster 500 that permits visualization and guidance during cataract surgery using CALLISTO eye. The ZEISS Cataract Suite markerless utilizes an ophthalmic surgical microscope and the following medical devices:

Indications for Use:

IOLMaster 500

The IOLMaster is intended for the biometric determination of ocular measurements of axial length, anterior chamber depth, corneal radius, white-to-white (WTW), and for the measurement of pupil size and deviation of the visual axis from the center of the pupil. For patients who are candidates for intraocular lens (IOL) implantation, the device also performs calculations to assist physicians in determining the appropriate IOL power and type for implantation.
This device is intended for use by physicians and eye-care professionals and may only be used under supervision of a physician.

CALLISTO eye
CALLISTO eye is an assistance system that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The system allows the remote control of the surgical microscope.

The graphical guidance tools, as displayed on the CALLISTO eye Panel PC or microscope eye piece, aid the surgeon to insert, align, position, and register an artificial lens. These tools are intended for anterior segment ophthalmic surgical procedures, including positioning and angular alignment of toric intraocular lenses, limbal relaxing incisions and capsulorhexis. The system utilizes surgeon information for position of graphical guidance tools.

Prescription Use __X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

2.0 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

Submitter's name, address, telephone number, contact person, and date summary prepared:

1. Applicant:
Carl Zeiss Meditec AG
Goeschwitzer Strasse 51-52
07745 Jena
Germany

2. Contact Person:
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Name of device, including trade name and classification name

1. Trade/Proprietary Name:
a. IOLMaster / IOLMaster 500
b. CALLISTO eye
c. Opthalmic Surgical Microscopes

2. Common/Usual Name:
a. Biometer
b. Picture Archiving and Communication System
c. Ophthalmic Surgical Microscope and accessories

3. Classification Name:
a. AC-powered slit lamp biomicroscope
b. System, Image management, Ophthalmic; Ocular Marker; Surgical Microscope
c. Surgical Microscope, operating & accessories, AC-powered, ophthalmic

4. Product Code and Class:
a. HJO – Class II
b. NFJ, HMR, EPT– Class II
c. HRM – Class I

5. Classification Number:
a. 21 CFR 886.1850
b. 21 CFR 892.2050
c. 21 CFR 878.4700

Predicate Device

The ZEISS Cataract Suite markerless is similar in function and application in cataract surgery to the predicate device, the TrueVision 3D Visualization and Guidance System (K101861). The visualization system displays real-time images during ophthalmic surgery on a flat-panel digital display device positioned for live video image viewing by the surgeon in the operating room.

Device Description

The markerless toric IOL alignment workflow provided with the ZEISS Cataract Suite markerless is a series of medical devices integrated into one workflow for use by a cataract surgeon. The workflow comprises an optical biometric device with green LED image capture from the IOLMaster 500 (K122418) with an optional accessory (Option Reference Image). The captured image is transferred to a cataract surgery assistance system, the CALLISTO eye (K123464), which operates in conjunction with ophthalmic surgical microscopes. Integrated or external data injection systems (IDIS or EDIS) are capable of displaying the graphical templates of the CALLISTO eye in the right ocular of the ophthalmic surgical microscopes.

Indications for Use

The ZEISS Cataract Suite markerless workflow uses a preoperative image capture tool from the IOLMaster 500 that permits visualization and guidance during cataract surgery using CALLISTO eye. The ZEISS Cataract Suite markerless utilizes an ophthalmic surgical microscope and the following medical devices:

IOLMaster 500

The IOLMaster is intended for the biometric determination of ocular measurements of axial length, anterior chamber depth, corneal radius, white-to-white (WTW), and for the measurement of pupil size and deviation of the visual axis from the center of the pupil. For patients who are candidates for intraocular lens (IOL) implantation, the device also performs calculations to assist physicians in determining the appropriate IOL power and type for implantation.

This device is intended for use by physicians and eye-care professionals and may only be used under supervision of a physician.

Indications for Use (cont.)

CALLISTO eye

CALLISTO eye is an assistance system that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The system allows the remote control of the surgical microscope.

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Comparison of Technological Characteristics

The ZEISS Cataract Suite markerless and the predicate device, the TrueVision 3D Visualization and Guidance System (K101861) share similar functional features and operating characteristics. The TrueVision system captures an image of the eye that is displayed by the 3D Visualization and Guidance System. As with the CALLISTO eye, the TrueVision 3D Visualization and Guidance System provides graphical templates and overlays that are viewed via an ophthalmic surgical microscope to aid the surgeon during cataract surgery.

Performance Data

The IOLMaster 500 and CALLISTO eye software were tested according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. The software testing also followed the Carl Zeiss Meditec internal software development procedure that is in compliance with the IEC 62304:2006 – Medical device software – Software life cycle processes.

Electromagnetic compatibility and safety testing was conducted along with appropriate bench testing to verify changes to the devices.

Conclusion

Based on the software verification and validation, safety testing and bench testing as well as the comparison to the predicate devices, the ZEISS Cataract Suite markerless as well as the contributing devices are safe and effective with respect to their Indications for Use.