DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 6, 2017

Carl Zeiss Meditec Ag
% Mr. Rahul Ram
Consultant
Biologics Consulting Group, Inc.
400 N. Washington Street, Suite 100
Alexandria, VA 22314

Re: K170171
Trade/Device Name: IOLMaster 700
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: January 18, 2017
Received: January 19, 2017

Dear Mr. Ram:

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,

Denise L. Hampton -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170171

Device Name
IOLMaster 700

Indications for Use *(Describe)*

The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures:

- Lens thickness
- Corneal curvature and thickness
- Axial length
- Anterior chamber depth
- Pupil diameter
- White-to-white distance (WTW)

For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye.

The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.

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.

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the IOLMASTER 700 is provided below.

Device Common Name:	Biometer
Device Trade Name:	IOLMASTER 700
Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena Germany
Contact:	Dr. Christian Muenster Director Regulatory and Clinical Affairs +49 7364 206985 christian.muenster@zeiss.com
Prepared by:	Rahul Ram Biologics Consulting Group rram@biologicsconsulting.com (571) 777-9518
Date Prepared:	April 5, 2017
Classification Regulation:	21 CFR 886.1850, Class II, AC-powered slitlamp biomicroscope
Panel:	Ophthalmology
Product Code:	HJO - AC-powered slitlamp biomicroscope.

Predicate Device:

Carl Zeiss Meditec AG IOLMASTER 700

K143275

Product Code: HJO - AC-powered slitlamp biomicroscope.

Indications for Use:

The indications for use are identical between the subject and predicate IOLMaster 700 devices.

The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures:

- Lens thickness
- Corneal curvature and thickness
- Axial length
- Anterior chamber depth
- Pupil diameter
- White-to-white distance (WTW)

For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye.

The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.

Device Description:

The IOLMaster 700 is a non-invasive optical biometry instrument for visualization and measurement of ocular structures. The IOLMaster 700 is the latest generation device in the IOLMaster series. The version of the IOLMaster 700 that is the subject of this submission is a modified version of the IOLMaster 700 cleared under K143275.

The differences between the subject IOLMaster 700 and the predicate IOLMaster 700 that are the subject of this 510(k) submission are:

- Labeling changes, including inclusion of additional clinical data and minor updates;
- Materials changes to the forehead rest and chin rest

The changes described in this submission do not affect how the hardware is used to acquire images, nor do these changes affect the principle of operation of the device.

Electrical Safety & Electromagnetic Compatibility:

The IOLMaster 700 was evaluated against the requirements of Edition 3.1 of IEC 60601-1 (IEC 60601-1:2005 + Amendment 1 (2012)), Edition 3.1 of IEC 60601-1-6 (IEC 60601-1-6:2010 + Amendment 1 (2013)) and Edition 1.1 of IEC 62366 (IEC 62366:2007 + Amendment 1 (2014)), and found to comply.

The IOLMaster 700 was evaluated against the requirements of Edition 4.0 of IEC 60601-1-2 (IEC 60601-1-2:2014) and found to comply.

Biocompatibility:

Testing was conducted as per the following biocompatibility standards:

- ISO 10993-10:2014 (skin irritation and sensitization)
- ISO 10993-5:2009 (cytotoxicity)

Testing demonstrated that the new materials are biocompatible for the proposed use.

Device Comparison Table:

DEVICE CHARACTERISTICS	PROPOSED IOLMASTER 700 (CARL ZEISS MEDITEC AG) K170171	PREDICATE IOLMASTER 700 (CARL ZEISS MEDITEC AG) K143275
Indications for Use	The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures: • Lens thickness • Corneal curvature and thickness • Axial length • Anterior chamber depth • Pupil diameter • White-to-white distance (WTW) For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.	Identical
Principles of Operation	Spectral domain interferometry (OCT principle), Light spot projection (infrared LEDs), Image capturing	Identical
Feature - Corneal Curvature Measurement (KER):		
Technology for obtaining measurements/images	Telecentric keratometry = distance independent, Light spot projection (infrared LEDs)	Identical
Keratometry algorithm		Similar
Feature - Lens Thickness Measurement (LT):		
Technology for obtaining measurements/images	Swept source laser Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical

DEVICE CHARACTERISTICS	PROPOSED IOLMASTER 700 (CARL ZEISS MEDITEC AG)	PREDICATE IOLMASTER 700 (CARL ZEISS MEDITEC AG) K143275
Feature - Central Corneal Thickness Measurement (CCT):		
Technology for obtaining measurement	Swept source laser Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical
Feature - Anterior Chamber Depth Measurement (ACD):		
Technology for obtaining measurement	Swept source laser Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical
Feature - Axial Length Measurement (AL):		
Technology for obtaining measurement	Swept source laser 1055 nm, Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan	Identical
Feature - Pupil Diameter Measurement (P):		
Technology for obtaining measurement	Image capturing of the iris with internal digital camera.	Identical
Feature - White-to-White Measurement (WTW):		
Technology for obtaining measurement	Image capturing of the iris with internal digital camera.	Identical
Feature - Reference Image Functionality:		
Technology for obtaining measurement	Green LEDs for green light illumination for image capturing of scleral vessels with internal digital camera.	Identical
Feature - Computational formulas	Haigis suite (includes Haigis, Haigis-L and Haigis-T); Hoffer Q; Holladay 2; SRK®/T	Identical
Electrical Data:		
Rated voltage / frequency	100 V to 240 V AC (± 10 %) / 50/60 Hz	Identical
Power consumption: Basic unit In standby mode	 150 W 1 W	Identical

Ambient conditions:		
for intended use	Temperature: 10°C to +35°C, Relative humidity: 30% to 80% (noncondensing)	Temperature: 10°C to +35°C, Relative humidity: 30% to 90% (noncondensing)
for storage and transport	Temperature: -20°C to +60°C, Relative humidity: 10% to 90% (noncondensing)	for storage: Temperature: -10°C to +55°C, Relative humidity: 10% to 95% (noncondensing) for storage and transport: Temperature: -40°C to +70°C, Relative humidity: 10% to 95% (noncondensing)
Material composition of patient interface with forehead rest and chin rest cap	ABS	PC/ABS Blend

Substantial Equivalence Summary:

Given the acceptable results of performance testing for the significant device modifications, we believe that the subject IOLMaster 700 is substantially equivalent to the predicate IOLMaster 700, cleared under K143275.