DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 31, 2017

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

Re: K162684
Trade/Device Name: SL 220
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: April 21, 2017
Received: April 24, 2017

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. 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 yours,

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)*

K162684

Device Name
SL 220

Indications for Use *(Describe)*

An AC-powered slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

a.	Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena Germany
b.	Contact Person:	Mandy Ambrecht Staff Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 mandy.ambrecht@zeiss.com Tel: (925) 557-4561
c.	Date Submitted:	April 21, 2017

Name of device, including trade name and classification name

a.	Trade/Proprietary Name:	SL 220
b.	Common/Usual Name:	Slit Lamp
c.	Classification Name:	AC-powered slit lamp biomicroscope
d.	Product Code and Class:	HJO – Class II
e.	Regulation Number:	886.1850

Predicate Devices
The SL 220 is substantially equivalent to the predicate devices Carl Zeiss Meditec (CZM) Slit Lamp SL 130 (K133476), and C.S.O. SL990 (K992836).

Device Description
The SL 220 can be used in performing a wide range of conventional eye care applications. It is used for ophthalmic observation of structural properties of the eye. The illumination can be adjusted from slit type illumination to a full-field type illumination by beam forming elements. The instrument is primarily used by ophthalmologists, opticians and optometrists.

Indications for Use
An AC-powered slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Comparison of Technological Characteristics
The SL 220 predicate devices, Carl Zeiss Meditec (CZM) Slit Lamp SL 130 (K133476) and C.S.O. SL990 (K992836), share similar functional features and operating modes.

The following main technological differences existing between the subject and predicate devices are:

- Top-illumination versus bottom-illumination
- Halogen versus LED illumination

The technical specifications of the SL 220 light sources are as follows:

	OPERATING CHARACTERISTICS		EXPOSURE CONDITIONS
LIGHT SOURCE	WAVELENGTH IN nm	MAXIMUM OUTPUT IN mW/cm^2	CONTINUOUS WAVE / PULSED
Slit lamp, LED	412 – 810	58.1	Continuous wave
DigiCam Illuminator, LED	405 - 900	1.18	Continuous wave
Fixation light, LED	540 – 720	< 0.03	Pulsed
Fixation light, Tungsten bulb	380 - 1700	0.03	Continuous wave

Brief Summary of Nonclinical Tests and Results
The SL 220 has demonstrated conformance to the following recognized performance standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR.2 (2007) + AM 1 (2012)
- IEC 60601-1-2: 2007 (Third edition)
- ISO 15004-2:2007

Conclusion
Based on the test results and the comparison to the predicate devices, the SL 220 including its accessories, is safe and effective with respect to its intended use when used in accordance with its Instructions for Use and substantially equivalent to, and performs as well as, the predicate devices.