DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 23, 2017

Carl Zeiss Meditec AG
Dr. Christian Muenster
Director Clinical & Regulatory Affairs
Rudolf-Eber-Strasse 11
73447 Oberkochen, Germany

Re: K161607
Trade/Device Name: Visulux
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: December 21, 2016
Received: January 12, 2017

Dear Dr. Muenster:

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)*
K161607

Device Name
VISULUX

Indications for Use *(Describe)*
The fiber slit illuminator is indicated for use as an alternative illumination system to the surgical microscope in ophthalmic microsurgery for procedures on the anterior and posterior segments of the eye. The fiber slit illuminator is not equipped with a light source, but uses the light transferred from the microscope by a light guide.

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
(as per 21 CFR §807.92)

VISULUX

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany +49 3641220-667 (phone) +49 3641220-282 (fax) Establishment Registration Number: 9615030
Contact Person:	Christian Muenster Director Clinical and Regulatory Affairs Carl Zeiss Meditec AG Rudolf-Eber-Strasse 11 73447 Oberkochen, Germany +49 7364-206985 Phone +49 7364 954432 Fax E-mail: christian.muenster@zeiss.com
Date prepared:	February 22, 2017
Classification Name:	Biomicroscope, Slit-lamp, AC-powered
Product Code and Class:	HJO – Class 2
Classification:	21 CFR 886.1850
Trade/Proprietary Name:	VISULUX
Predicate Device	SL 115 Classic slit lamp Manufactured by Carl Zeiss Meditec
Predicate 510(k) Number	K133476

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

The VISULUX is intended to be used together with a microscope to perform ophthalmic observations. The device is primarily used by surgical ophthalmologists. As the device has no own light source the microscope must provide an additional separate light source or at least a separate S-light guide to be connected to the VISULUX.

The released devices for mounting the VISULUX are as followed:

- OPMI Lumera 700
- OPMI Lumera T on S8, S81 or S88 stand
- OPMI VISU 210 on S8, S81 or S88 stand
- OPMI VISU 200 (Brightflex) on S8, S81 or S88 stands
- OPMI VISU 160 on S8, S81 or S88 stands
- OPMI VISU 150 (Brightflex) on S8, S81 or S88 stands

All these devices are Class I devices and are listed under the establishment number 9615010 (Carl Zeiss Meditec AG), regulation number 878.4700.
All microscopes consist of the microscope itself and a floor stand or a ceiling mount. As a rule the light sources are integrated in the floor stand or ceiling mount. This light source is also used to feed the VISULUX.

Regarding the OPMI Lumera 700 the floor stand and ceiling mount is not named separately as it is designed especially for the OPMI Lumera 700. Also here the importing item is the floor stand as in here the light source is integrated. OPMI Lumera 700 is a product consisting of microscope and stand. Based on this the stand is not listed or named separately.
The light is brought by a light guide in the device and is channeled through an optical system to leave the device as a bright, sharp slit. The operator can adjust the beam with a slideable aperture to have different widths.

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

The fiber slit illuminator is indicated for use as an alternative illumination system to the surgical microscope in ophthalmic microsurgery for procedures on the anterior and posterior segments of the eye. The fiber slit illuminator is not equipped with a light source, but uses the light transferred from the microscope by a light guide.

RISK MANAGEMENT

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. VISULUX has an own Instruction for Use.

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.

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

VISULUX is substantially equivalent in intended use, mechanism of action and principle of operation to the cleared device from Carl Zeiss Meditec, SL 115 Classic slit lamp (K133476). This predicate has not been subject to a design-related recall.

Each system produce a bright, sharply delimited slit image for high-contrast observation through the surgical microscope. VISULUX itself has no surgical microscope but uses the device where it is attached to.
The predicate is a stand-alone slit lamp including a surgical microscope.

VISULUX has no own light source. The microscope where the VISULUX is attached to must provide a separate light source and a separate S light guide to be connected to.

The predicate has its own light source.

Evaluation performed on the VISULUX supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness.

SUMMARY OF PERFORMANCE DATA (21 CFR §807.92(B))

The following performance data were provided in support of the substantial equivalence determination.

- **ISO 14971:2007** is a general standard with no specific test acceptance criteria. This standard was used to demonstrate compliance with risk management processes and to support ANSI/AAMI ES60601-1 and IEC 60601-1-2.

- **ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012**
  Basic safety and essential performance has been evaluated for the VISULUX. VISULUX has been found to be in compliance with the ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 standard.

- **IEC 60601-1-2:2007**
  Electromagnetic compatibility (EMC) has been evaluated for VISULUX. VISULUX has been found to be in compliance with the IEC 60601-1-2:2007 standard.

- **ISO 10939:2007**
  The ISO 10939, applicable for ophthalmic instruments and in particular Slit-lamp microscopes has been evaluated for the VISULUX. It was made in conjunction with all applicable light sources (LED, Halogen and Xenon). The VISULUX has been found to be in compliance with the ISO 10939 standard.

- **ISO 15004-2:2007**
  The ISO 15004-2, describing Fundamental requirements and test methods for Light hazard protection has been evaluated for the VISULUX. The device has been found to be in compliance with ISO 15004-2 standard.

- **IEC 62366-1:2015**
  IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices is a general standard with no specific test acceptance criteria. This standard was used to demonstrate compliance to human factors engineering processes, commonly known as "Usability Engineering" applicable to the product design and development process.

- **Software Verification and Validation Testing**
  VISULUX does not contain software

- **Animal Study**
  Animal Studies were not conducted for this device as it is not needed to support substantial equivalence to the predicate devices.

- **Clinical Studies**
  Clinical Studies were not conducted for this device as it is not needed to support substantial equivalence to the predicate devices.

Conclusion

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the VISULUX should perform as intended in the specified use conditions.

The data demonstrate that the VISULUX performs comparably to the predicate device that is currently marketed for the same intended use.

SUBSTANTIAL EQUIVALENCE TO PREDICATE (21 CFR §807.92(B)(1)):

As previously indicated VISULUX has been tested to meet the product requirements (PRS) and is considered to be substantially equivalent to the predicate as indicated above.

510(K) SUMMARY (21 CFR §807.92(C)):

In summary, based on the successful verification and validation testing, it is Carl Zeiss Meditec AG's opinion that VISULUX does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate device.

Additionally, all testing deemed necessary was conducted on VISULUX to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate device.