January 13, 2023

Olympus Winter & Ibe GmbH
% Christina Flores
Manager Regulatory Affairs
Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K223183
Trade/Device Name: Light-Guide Cables
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: HBI
Dated: October 10, 2022
Received: October 12, 2022

Dear Christina Flores:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang -S

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223183

Device Name

Light-Guide Cables (WA03300A, WA03310A)

Indications for Use *(Describe)*

Transmission of light energy from the light source to an optical instrument.
The light-guide cable is used to transmit light during endoscopic procedures or for other medical illumination application when the properties and operating instructions are complied with.
The light-guide cable is designed for use with halogen, xenon or LED based light sources of cold light which are utilized in medical applications that involve endoscopes, medical instruments or microscopes.

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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K223183

510(k) Summary of Safety and Effectiveness
September 21, 2022

1. General Information

Manufacturer:	Olympus Winter & Ibe GmbH Kuehnstr. 61 22045 Hamburg Germany Establishment Registration Number: 9610773
Official Correspondent:	Christina Flores, RAC Manager Regulatory Affairs Olympus Surgical Technologies of the Americas 800 West Park Drive Westborough, MA 01581 Phone: (508) 808-3341 Email: Christina.Flores@olympus.com Establishment Registration No. 3003790304

2. Device Identification

Common Name:	Light-Guide Cables
Regulation Number	21 CFR 878.4580
Classification:	Illuminator, Fiberoptic, Surgical Field Surgical Lamp
Device Class	II
Product Code	HBI
Review Panel	General & Plastic Surgery
Proprietary/Trade Name	Light-Guide Cables

Model numbers: WA03300A, WA03310A

3. Predicate Devices

The predicate device was chosen from the following predicate 510(k):

510(k) No.	Name	Predicate Model No.	Product code / Reg No.
K111342	Light Guide Cable Schott North America	not stated in K111342	HBI / 21 CFR 878.4580

These predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

4. Product Description

The Olympus Light-Guide Cables that are subject to this submission are intended to transmit light from the light source to an optical instrument. For that purpose the Light-Guide Cable includes a bundle of optical fibers as transmission medium. The light guide adapters are intended for the mechanical connection of the Light-Guide Cables to light sources or to endoscopes.

There are two variants of Light-Guide Cables which differ according to the shaft diameter of the connected endoscope. Cable WA03300A (2.8 mm, 3 m, CF type) can be combined with endoscopes, which have a diameter ≤ 4.1mm. Endoscopes with a diameter > 4.1mm are combined with WA03310A (4.25 mm, 3 m, CF type). Otherwise the Light-Guide Cables are identical.

5. Indications for Use

Transmission of light energy from the light source to an optical instrument. The light-guide cable is used to transmit light during endoscopic procedures or for other medical illumination application when the properties and operating instructions are complied with. The light-guide cable is designed for use with halogen, xenon or LED based light sources of cold light which are utilized in medical applications that involve endoscopes, medical instruments or microscopes.

6. Comparison of Technological characteristics

The subject and predicate device K111342 are based on the same technological principle with the same elements:

- In both cases an illumination of the operation field by transmitting of visual light is indicated during surgical procedure or endoscopic diagnosis/therapy.
- Dimensions differ.
  Subject Device: WA03300A: 2.8 mm, 3 m, CF type; and WA03310A: 4.25 mm, 3 m, CF type.
  Predicate Device: 1,8m - 3m depending on device model.
- Both devices consist of fused optical fibers: Glass fibers fused into fenules on both ends. The ends are polished to transmit light.
- The subject and predicate device both use the same type of fiber: GOF85
- Fiber cross section of subject and predicate device. The fiber cross-section results in a different amount of brightness.

- The Light-Guide Cables use the same materials for the outer tube: Silicone
- The Light-Guide Cables use the same materials for the connector: stainless steel.
- Both devices are not have patient contact and no patient contacting materials.
- Both devices stating different combination information. The subject device is provided in a "ready to use" state in combination with Olympus products.
- The subject device has an additional Olympus connector and additional inner stainless steel wire for better mechanical protection
- Design changes of the cables are minor and do not negatively impact safety or effectiveness of the subject devices

As stated above, the subject and predicate devices have similar design characteristics and performance specifications, with the exception of the cross-sections, variations of the cables in length and dimension and an additional stainless steel wire in the subject device. These minor differences, however, do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing (e.g. electrical safety, Bench Testing, reprocessing validation) and the Substantial Evidence Discussion (Section 6), the different technological characteristics do not affect the safety and effectiveness of the subject devices.

Based on the information presented above, Olympus Winter & Ibe GmbH believes that the subject device Light-Guide Cables are substantially equivalent to the cited predicate device (K111342) and that the differences between devices are minor and raise no new issues of safety or effectiveness.

7. Performance Data

The Light-Guide Cables comply with all applicable requirements/standards as listed in **Appendix IIIc** of this submission.

The design of the subject device Light-Guide Cables is identical to that of the predicate devices. As described in detail in **Section 6** of this submission, the only differences between the Light-Guide Cables subject to this submission and the predicate Light-Guide Cables from K111342 are minor design modifications. Furthermore this premarket submission is submitted by Olympus to clear a new sterilization method. Currently the subject devices in this submission are covered in K111342 submitted by Schott. Because of that, Olympus Light-Guide Cables such as the predicate devices have been used safely and effectively for years.

In view of the above, it was not considered necessary to re-test the performance of the Light-Guide Cables concerned. However, complete evidence of the performance test records is included in this submission.

Respective test records are referenced and are provided in **Appendix 12a-e**.

8. Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety was tested according to

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-2-18: Edition 3.0 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

9. Reprocessing, Sterilization and Shelf Life

The Light-Guide Cables are delivered in unsterile condition and thus have no shelf life, but rather a defined lifetime. This lifetime can be specified as a certain number of cycles for reprocessing. For the Light-Guide Cables, the expected service lifetime is 400 reprocessing cycles.

The products are delivered in unsterile condition and should be reprocessed before first and each subsequent use. The product should be cleaned manually or automatically, before being inspected and then sterilized with steam or hydrogen peroxide plasma. Validated Sterilization methods for Light-Guide Cables WA03300A and WA03310A are Hydrogen peroxide plasma sterilization (Sterrad 100S, Sterrad NX, Sterrad 100NX), Steam Sterilization (Autoclave, prevacuum) and Vaporized hydrogen peroxide (Steris V-PRO maX, Steris V-PRO maX 2, Steris V-PRO s2 and Steris V-PRO 60).

Olympus recommends automated cleaning and steam sterilization for this product.

10. Conclusion

The performance data support the safety and effectiveness of the subject device and demonstrate that the subject device is substantially equivalent to the predicate device.

In conclusion, the Light-Guide Cables are substantially equivalent to the predicate device.