January 19, 2023

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

Re: K221522
Trade/Device Name: HF-cables (reusable)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: December 20, 2022
Received: December 20, 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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
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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)*
K221522

Device Name
HF-cables (reusable)

Indications for Use *(Describe)*
HF cables for electrosurgical use in laparoscopic, endoscopic, and open surgery in combination with compatible active accessories and compatible electrosurgical generators

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.

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510(k) Summary of Safety and Effectiveness

2.1 General Information

Manufacturer/Holder

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Germany
Establishment Registration No.: 9610773

Official Correspondent

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2.2 Device Identification

Common Name:	HF-cables (reusable)
Regulation Number:	21 CFR 878.4400
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Class:	II
Product Code:	GEI
Review Panel:	General & Plastic Surgery
Proprietary/Trade Name:	HF-cables (reusable)

Table 2.1: List of devices subject to this submission

Article No.	Article name
A00010A	HF-cable, monopolar
A00011A	HF-cable, monopolar
A00012A	HF-cable, monopolar
A0335.1	HF-cable, monopolar
A0355	HF-cable, monopolar

Article No.	Article name
A0357	HF-cable, monopolar
A0358	HF-cable, monopolar
A0391	HF-cable, monopolar
A0392	HF-cable, monopolar
A0393	HF-cable, monopolar
A60000C	HF-cable, bipolar
A60001C	HF-cable, bipolar
A60002C	HF-cable, bipolar
A60003C	HF-cable, bipolar
WA00013A	HF-cable
WA00014A	HF-cable, bipolar

2.3 Predicate Device

The HF-cables (reusable) subject to this submission **Table 2.1** are considered substantially equivalent to the following legally marketed predicate device identified in **Table 2.2**.

Table 2.2: Predicate Device

Predicate Device	Device Name	510(k) No.
WA00014A	HF-cable, bipolar	K120418

2.4 Device Description

The HF-cables (see **Table 2.1**) subject to this submission are reusable, non-sterile devices, that connect electrosurgical generators as sender to compatible active accessories as receiver for electrosurgical use in laparoscopic, endoscopic, and open surgery. The devices are used as part of a system.

The HF-cables are class II medical device accessories under the regulation number 878.4400 and the product code GEI – “Electrosurgical cutting and coagulation device and accessories”. Regulation Medical Specialty: General & Plastic Surgery.

There are monopolar as well as bipolar HF-cable models subject of this submission. All of the subject HF-cables are delivered non-sterile. They are reusable and fully autoclavable. Before first and each subsequent use the cables must be inspected and reprocessed according to defined reprocessing methods in the Instructions for Use.

The HF-cables are available with different cable lengths and with different plugs for the working element/instrument as well as for the electrosurgical generator side. The different plugs allow

different compatibilities in accordance with their respective labeling.

2.5 Intended use and indications

HF cables for electrosurgical use in laparoscopic, endoscopic, and open surgery in combination with compatible active accessories and compatible electrosurgical generators.

The indications for use statement for the subject HF-cables is comparable to that of the predicate device. A slightly different wording is chosen and specific indications are added. Furthermore, the sentence “Do not use for any other purposes.” was removed.
The differences do not alter the intended use of the devices nor do they raise different questions of safety and effectiveness of the device relative to the predicate.

2.6 Summary of Technological Characteristics

The technological characteristics of the subject devices are considered equivalent to the predicate device.

The subject devices and predicate device share the following characteristics:

- general technology (HF-cables connecting electrosurgical generators as sender to compatible active accessories as receiver for electrosurgical use),
- validated reprocessing methods, and
- expected service life.

The following differences to the predicate device exist depending on the subject device model:

- design of plugs (different configurations of plugs for connectivity to the compatible instrument and the electrosurgical generator of each HF-cable),
- max. rated voltage (only different for monopolar subject devices),
- electrical resistance,
- cable weight,
- comparable cable length,
- wire cross section,
- number of single wires, and
- cable diameter/cable cross section.

As stated above, the subject and predicate devices have similar design characteristics and show comparable performance. As demonstrated in the non-clinical testing the different technological characteristics do not negatively alter the safety and effectiveness of the subject device.

2.7 Performance Data

Performance tests were carried out to ensure that the subject devices function as intended and meet design specifications. The following performance data were provided in support of the substantial equivalence determination.

■ Biocompatibility Testing

The HF-cables do not contain components that come directly or indirectly in patient contact. Biocompatibility testing according to ISO 10993 is not required.

■ Electrical Safety

The subject HF-cables have been successfully tested for electrical safety in accordance with AAMI/ANSI and IEC 60601 standards (please see list of applied FDA recognized standards below).

■ Thermal Safety

The subject HF-cables have been successfully tested for thermal safety in accordance with AAMI/ANSI and IEC 60601-1:2005/(R)2012 standards (please see list of applied standards below).

■ Performance Testing Bench

Conducted tests include tests with regard to design, transport and storage, repeated stress and mechanical performance testing.

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971.

■ Reprocessing

Required cleaning and sterilization procedures for the HF-cables are described in the respective instructions for use. All described methods are supported by respective validation test reports.

■ Applied Standards

Table 2.3: Applied FDA recognized standards

Standards Number	Standard Title	FDA-Recognition Number + date
AAMI/ANSI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4 07/09/2014
IEC 60601-1-2 Ed. 4.0: 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8 09/17/2018
IEC 60601-2-2 Ed. 6.0: 2017-03	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	6-389 06/07/2021
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89 06/27/2016
IEC 62366-1 Edition 1.0 2015-02	Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114 12/23/2016
ISO 14971 Second edition 2007-03-01	Medical devices – Application of risk management to medical devices	5-40 06/27/2016
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	2-258 01/14/2019
ISO 15223-1 Third edition 2016-11-01	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	5-117 08/21/2017
ISO 17664 Second edition 2017-10	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	14-515 07/06/2020
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	14-499 12/23/2016

2.8 Conclusion

The performance data demonstrates the safety of the device as well as compliance with listed recognized consensus standards.

In summary, Olympus believes the subject HF-cables are substantially equivalent to the predicate device with respect to the general design approach, function, and the intended use. The subject HF-cables raise no new concerns of safety or effectiveness compared to the predicate device.