November 16, 2017

Olympus Winter & Ibe GmbH
% Dolan Mills
Sr. Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K172535
Trade/Device Name: Bipolar applicator "CELON ProCurve V"
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 10, 2017
Received: November 13, 2017

Dear Dolan Mills:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K172535

Device Name
Bipolar applicator "CELON ProCurve V"

Indications for Use *(Describe)*
The bipolar applicator, in combination with the compatible electrosurgical generator, is indicated for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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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K172535

510(k) Summary of Safety and Effectiveness

November 10, 2017

2.1 General Information

Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany
Establishment Registration Number: 9610773

Official Correspondent:
Dolan Mills
Sr. Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772-2104
Phone: 901.373.0236
Fax: 901.373.0220
Email: dolan.mills@olympus-osta.com
Establishment Registration Number: 3003790304

2.2 Device Identification

Proprietary name:	Bipolar applicator "CELON ProCurve V"
Common name:	CELON ProCurve V
Device Classification name:	Electrosurgical, Cutting & Coagulation & Accessories
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400
Device class:	Class II
Product code:	GEI
Model Number:	WB990207

2.3 Predicate Device

The CELON ProCurve V is considered substantially equivalent to K111887, GEI, 21CFR 878.4400:

Covidien (Medtronic) CLOSUREFAST™ ENDOVENOUS RADIOFREQUENCY ABLATION CATHETER

According to public information this device is currently available in the US market and is designed to be used for endovascular coagulation of blood vessels in patients with superficial vein reflux.

No reference devices were used in this submission.

2.4 Device Description

The CELON ProCurve V is a bipolar applicator that uses Radiofrequency Induced Thermotherapy (RFITT) technology for treating varicose veins. The medical purpose of the Radiofrequency Induced Thermotherapy is to achieve controlled tissue coagulation. The CELON ProCurve V is used in conjunction with a compatible generator.

2.5 Indications for Use

The subject device has the same intended use as the predicate device.

"The bipolar applicator, in combination with the compatible electrosurgical generator, is indicated for endovascular coagulation of blood vessels in patients with superficial vein reflux."

2.6 Comparison of Technological Characteristics

The technological characteristics of the CELON ProCurve V are considered equivalent to the predicate device. Both the CELON ProCurve V and the predicate device share the following characteristics:

- fundamental scientific technology (bipolar electrosurgery)
- principles of operation (endovascular coagulation of blood vessels with a catheter electrode)
- used in conjunction with an electrosurgical generator.
- Comparative testing demonstrated that the subject device has equivalent performance to the predicate in respect to applicable modes.

The following differences to the predicate device exist:

- While using radiofrequency technology for coagulation, the predicate device uses the heat generated through the radiofrequency current.
- While the CELON ProCurve V is pulled slowly and steadily back through the vein and activated the whole time, the predicate device is placed at the first desired position and activated. Afterwards the predicate devices is

pulled back further until the next desired position within the vein and activated again.
- minor dimensional differences exist between the subject and the predicate device

As stated above, the subject and proposed predicate devices have similar design characteristics and show comparable performance. As demonstrated in the non-clinical testing (e.g., biocompatibility, tissue effects), the different technological characteristics do not negatively affect the safety and effectiveness of the subject device.

2.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination. All standards applied are FDA recognized international standards.

Performance data was prepared in accordance with the FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, issued on August 15, 2016. The guidance was followed for all relevant sections.

2.7.1 Biocompatibility testing

The patient contacting materials of the CELON ProCurve V have been successfully tested or assessed for biocompatibility in the following tests in compliance with ISO 10993 standards:

- Cytotoxicity
- Chemical Analysis
- Sensitization – assessed by biological-toxicological evaluation
- Irritation – assessed by biological-toxicological evaluation
- Acute systemic toxicity – assessed by biological-toxicological evaluation
- In vitro Hemocompatibility (thrombogenicity)
- Hemolysis

Testing was done in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"”, CDRH June 16, 2016.

The device is considered external communicating, blood path / indirect, for a duration of less than 24 hours.

2.7.2 Electrical safety and electromagnetic compatibility (EMC)

The design of the CELON ProCurve V complies with recognized 60601 standards as listed in section 2.7.8.

The FDA guidance "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices", CDRH July 11, 2016 has been followed.

2.7.3 Thermal Safety

The design of the CELON ProCurve V complies with recognized standard IEC 60601-2-2 as listed in section 2.7.8.

2.7.4 Clinical Studies

Clinical and animal studies were not necessary.

2.7.5 Software

The CELON ProCurve V does not contain software.

2.7.6 Performance Testing Bench

Performance tests were executed to ensure that the device functioned as intended and met design specifications. The following non-clinical and preclinical tests were conducted:
1) non-clinical (electrical, dimensional, functional, biocompatibility, stability)
2) preclinical (simulated use) evaluation and testing of tissue effects and thermal safety

Non-clinical: Basic safety and performance testing was performed in accordance with IEC standards. In addition, verification and comparison bench studies were conducted to evaluate the functional performance.

Stability: Sterile samples were subjected to accelerated aging to confirm that the disposable devices maintain functionality and continue to meet specifications over time. The results of the accelerated age testing demonstrate that the device will be stable for the stated shelf-life. In addition, real time age testing will confirm the results of the accelerated age testing. Samples were also subjected to environmental conditioning and ship testing.

Preclinical: Evidence obtained from preclinical simulated use studies demonstrate that the device performs substantially equivalent to the predicate device in relevant aspects associated with usability, tissue effects, and thermal effects. For simulated use testing, three tissue types (porcine muscle, liver, and kidney) were evaluated in all applicable modes. The quality of intraluminal use was also verified for the applicable modes. The tissue effects testing included quantitative and qualitative assessment.

The ex vivo bench tests were based on three generator modes and three power settings which were applied five times to each of three different types of tissue. The

testing demonstrated comparable performance and tissue effects to the predicate. Additionally, in order to verify the quality of the intraluminal use ten ex vivo bench tests based on three generator modes and three power settings were applied to intraluminal animal tissue which also showed comparable performance and tissue effects. All tests passed.

To demonstrate substantial equivalence tissue effects were compared during comparative validation testing. The simulated use testing established substantial equivalence with the predicate device for the intended use based on an assessment of non-clinical performance data, as per 807.92(b).

These comprehensive validation bench tests support equivalence to the predicate device. Testing confirmed that comparable tissue effects could be achieved for applicable modes of operation.

Usability and user interface was also assessed according to the risk management plan. The assessment was based on Olympus predecessor product. Use-related hazardous situations were assessed and risk mitigation measures in terms of usability design for safety were defined. The residual risk was evaluated as acceptable. Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971:2007.

2.7.7 Reprocessing/ Sterilization

The CELON ProCurve V is sold in sterile condition and is defined as single use only and to be disposed of after use. Sterilization is performed according to ISO 11137-1 and packaging conforms to ISO 11607-1. The ionizing radiation (GAMMA rays) sterilization cycle has been validated. A sterility assurance level (SAL) of 10^{-6} was reached during validation and will be used for routine sterilization in compliance with regulations in force for sterile medical devices. Shelf Life testing was conducted, including performance testing and package integrity testing, to support a shelf life of 3.25 years for the CELON ProCurve V.

2.7.8 Applied standards

Standard No.	Standard Title	FDA-Recognition no + date
AAMI/ANSI ES 60601-1:2005 and A1:2012, C1:2009 and A2:2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4 07/09/2014

Standard No.	Standard Title	FDA-Recognition no + date
IEC 60601-1-2 Ed. 3.0 b: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-1 06/27/2016
IEC 60601-2-2 Ed. 5.0: 2009	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 [Including: Technical Corrigendum 1 (2014)]	6-336 01/27/2015
IEC 60601-1-6 Ed. 3.1: 2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89 06/27/2016
ISO 14971 Second edition 2007	Medical devices - Application of risk management to medical devices	5-40 06/27/2016
ISO 10993-1 Fourth Edition 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-220 07/26/2016
ISO 11607-1 First Edition 2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]	14-454 01/27/2015
ISO 11137-1 First Edition 2006	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013)]	14-428 04/04/2016
IEC 62366 Edition 1.1 2014-01	Consolidated Version Medical Devices - Application Of Usability Engineering To Medical Devices.	5-87 12/23/2016
ISO 10993-4 Second Edition 2002-10-15 AMENDMENT 1	Biological Evaluation Of Medical Devices - Part 4: Selection Of Tests For Interaction With Blood [Including: Amendment 1 (2006)].	2-235 07/26/2016
AAMI ANSI ISO 10993-5:2009/ (R)2014	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	2-153 07/26/2016
ISO 10993-12 Fourth Edition 2012-07-01	Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials	2-191 07/26/2016
ISO 10555-1 Second Edition 2013-06-15	Intravascular Catheters -- Sterile And Single-Use Intravascular Catheters -- Part 1: General Requirements. (General Plastic Surgery/General Hospital)	6-301 08/14/2015

Table 2.1.8: Applied standards

2.8 Conclusion

The performance data supports the safety of the device and demonstrates that the subject device complies with the recognized standards as specified.

In summary, we believe the CELON ProCurve V is substantially equivalent to the predicate device with respect to the general design approach, function, and the intended use. Differences between subject device and predicate do not negatively affect the safety and effectiveness of the subject device and raise no new questions of safety or effectiveness.