May 7, 2020

Covidien, LLC
Liron Bar Yaakov
Senior Manager Regulatory Affairs
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K200146
Trade/Device Name: HET Bipolar Electrocautery Forceps, HET Bipolar Electrocautery Monitor
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 2, 2020
Received: April 3, 2020

Dear Liron Yaakov:

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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200146

Device Name
HET™ Bipolar Electrocautery Forceps and Monitor

Indications for Use *(Describe)*

The HET Bipolar System is intended to be used for the treatment of symptomatic grade I and grade II internal hemorrhoids.

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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510(k) Summary – K200146

Date Prepared: May 5th, 2020

Submitter's Name and Address:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person:

Liron Bar Yaakov
Senior Manager, regulatory Affairs
Phone: (720) 422-9135
Fax: (408) 328-7310

Name of Device:

Proprietary Name: HET™ Bipolar Electrocautery Forceps and Monitor
Common/Usual Name: Electrosurgical Instrument
Classification Panel: General & Plastic Surgery
Device Regulation: 21 CFR 878.4400, Class II
Product Code: GEI

Establishment Registration Number, Owner/Operator Number:

Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497
The HET™ Bipolar System is manufactured by a contract manufacturer, Contract Medical Manufacturing, LLC (CMM). The CMM facility is located at:
1 Jacks Hill Road – Unit 3e
Oxford, CT 06478
The CMM facility has been assigned establishment registration number 3006183537 and Owner/Operator number 10042275.

Predicate Device(s):

K140422 HET™ Bipolar Electrocautery Forceps and Monitor

Device Description:

The HET™ Bipolar Forceps is a sterile, single-use bipolar forceps having a tapered tubular configuration. The device is connected via an integrated bipolar cable to the bipolar output of an electrosurgical generator. The accessory monitor displays the temperature at the forceps-tissue interface and provides power for a temperature sensor and an LED light source mounted on the disposable forceps. The HET™ Bipolar Electrocautery Forceps and Monitor do not generate RF energy themselves and may be used with any Bipolar Electrosurgical generator in the coagulation power setting with an output power set at 10 W and a maximum voltage of 1250V.

Indications for Use:

The HET Bipolar System is intended to be used for the treatment of symptomatic grade I and grade II internal hemorrhoids.

Technological Characteristics of the Device Compared to Predicate Device

The technological characteristics of the device are unchanged (*i.e.* are exactly the same) as compared to the characteristics of the predicate device that was cleared under 510(k) K140422. The purpose of this submission is to limit the indication within the previously cleared indications to treatment of symptomatic grade I and grade II internal hemorrhoids and to clarify that the action performed by the HET Bipolar Electrocautery Forceps and Monitor is considered as tissue ligation. The materials, software, and treatment mechanism (i.e., bipolar energy used to produce heat) are unchanged. Both the predicate device and the subject device use thermal energy delivered during forceps tissue clamping/compression to achieve the treatment effect, on the same target tissue and patient population. Both the subject device and the predicate device are indicated for the treatment of internal hemorrhoids.
As the subject device is identical to the predicate device, biocompatibility studies, software validations, and electrical safety studies previously reported and cleared for the predicate device remain applicable to the subject device.

Performance Data

Performance testing was conducted and reported in the 510(k) Notice for the predicate device K140422. Testing was conducted to characterize the device's performance when used in conjunction with eight FDA cleared, commercially available, bipolar electrosurgical generators. The studies evaluated to zone of thermal injury and confirmed that the treatment time was acceptable to allow safe treatment. Because the two devices are identical, the labeling updates provide clarifications and consistency with the revised indication for use and do not change the intended use of the device, user population or patient population. The information reported for the predicate device is applicable to the subject device. Additional testing was provided to support conformance to the latest revision of IEC 60601-1-2:2014.

Biocompatibility

Testing was previously conducted, and reported in the 510(k) K121085, to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, intracutaneous irritation, sensitization, acute systemic toxicity and hemocompatibility.

Sterilization

The HET™ Bipolar Forceps are sterilized with EtO to a sterility level of 10^{-6}.

Conclusion

The subject device has the same intended use and the identical design as the legally marketed predicate device. The labeling changes made to the subject device do not raise different kinds of safety and effectiveness questions. Therefore, Covidien llc considers the subject device, the HET™ Bipolar Electrocautery Forceps and Monitor, to be substantially equivalent to the legally marketed predicate device, the HET™ Bipolar Electrocautery Forceps and Monitor (K140422).