DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Covidien
Ms. Nancy Sauer
Regulatory Affairs Product Manager
5920 Longbow Drive
Boulder, Colorado 80301

August 4, 2015

Re: K150735
Trade/Device Name: Force Triverse Electrosurgical Device, Holster, 10-foot
Force Triverse Electrosurgical Device, Holster, 15-foot
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 29, 2015
Received: July 1, 2015

Dear Ms. Sauer:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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" (21CFR 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,

Joshua C. Nipper -S

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)*
K150735

Device Name
Force Triverse Electrosurgical Device, Holster, 10-foot
Force Triverse Electrosurgical Device, Holster, 15-foot

Indications for Use *(Describe)*

The Force TriVerse Electrosurgical Device is a single-use device intended for use in open surgical procedures (such as general, urologic, thoracic, plastic and reconstructive, gynecologic), and minimally invasive arthroscopic procedures where the surgeon desires monopolar radio-frequency electrosurgical energy to cut and/or coagulate tissue. The electrosurgical device is intended for use with conventional monopolar electrosurgical electrodes.

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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K150735

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510(k) Summary

Date summary prepared: 6/25/15

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

Nancy Sauer
Regulatory Affairs Product Manager
Telephone: 303-581-6791
Fax: 303-530-6313
Email: nancy.sauer@covidien.com

Name of Device

Trade Name:	Force TriVerse™ Electrosurgical Device
Catalog Numbers:	FT3000 and FT3000DB
Common Name:	Monopolar Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI).

Predicate Devices

These devices are legally marketed devices, manufactured by Covidien llc. The Force Triverse devices were originally cleared for marketing under 510(k) K051627. These instruments serve as their own predicate devices.

Device Description

The Force TriVerse Electrosurgical Devices are radiation-sterilized, single-use, hand-held monopolar electrosurgical instruments. There are two models—FT3000 and FT3000DB. These models are identical except for the cord length. FT3000 has a 10-ft cord and FT3000DB has a 15-ft cord.

The instruments work with compatible electrosurgical generators to cut and coagulate tissue during surgical procedures. The surgeon uses the controls on the handset to select the electrosurgical mode and to adjust the power output from within the surgical field. The surgeon selects the desired electrosurgical mode by pressing one of three buttons. The surgeon controls the power level using a slider control on the instrument body. The device is assembled with a blade electrode. The surgeon is able to replace this electrode with other standard monopolar electrodes as needed for a specific surgical procedure.

The device is provided with a safety holster to provide a safe location for storing the instrument when it is not in use.

Indications for Use

This 510(k) is for changes to the indications for use of these devices. The primary change is to remove references to compatible devices and electrodes. The statement has also been revised for clarity and consistency. The new indications for use statement is:

> The Force TriVerse Electrosurgical Device is a single-use device intended for use in open surgical procedures (such as general, urologic, thoracic, plastic and reconstructive, gynecologic) and minimally invasive arthroscopic procedures where the surgeon desires monopolar radio-frequency electrosurgical energy to cut and/or coagulate tissue. The electrosurgical device is intended for use with conventional monopolar electrosurgical electrodes.

Technological Characteristics

The Force TriVerse™ Electrosurgical Devices work in conjunction with Covidien electrosurgical generators. They use monopolar radiofrequency energy to cut and coagulate tissue. The devices provide controls that allow the surgeon to select one of three electrosurgical modes (cut, coagulate, or hemostasis with division, also known as Valleylab mode) and to control the power output from within the surgical field. The instrument connects to the generator by a 10-foot or 15-foot long cord, which has a proprietary connector. The Covidien generator recognizes the instrument through the connector and activates a unique user interface screen. The surgical team uses the combination of the generator user interface screen and the controls on the instrument to achieve the intended surgical effect (electrosurgical mode and power).

The instruments are rated for a maximum peak voltage of 3625 volts and when used with the specified generators, they meet the IEC 60601-1 criteria for Type CF applied parts.

The overall functionality and performance characteristics of the device are unchanged relative to the initially cleared device. However, some changes have been made in in materials used in the internal circuitry and the cable to improve manufacturability and reliability. Also, the safety holster packaged with the instrument has been made wider to more easily accommodate the cable during packaging.

Performance

Evidence of safety and effectiveness was presented in the previously submitted 510(k), which also demonstrated the compatibility of these instruments with the ForceTriad™ Energy Platform. Additional testing has been completed to demonstrate that the device still performs as expected following the design changes. The testing included:

- Testing in accordance with applicable clauses of IEC 60601-1
- Testing in accordance with applicable clauses of IEC 60601-2-2
- Testing in accordance with applicable clauses of IEC 60601-1-2
- Mechanical testing (such as mechanical strength, integrity of connections, performance of button and slider controls, resistance to fluids, and label adhesion)
- Shipping tests to verify that the packaging adequately protects the device
- Biocompatibility testing of direct and indirect patient-contacting materials (cytotoxicity, intracutaneous reactivity, sensitization, hemolysis, and acute systemic injection)

Conclusion

The current version of the device and its labeling remains substantially equivalent to the original design and labeling.