DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 10, 2016

TVA Medical, Inc.
Ms. Katherine Kumar
VP of Regulatory & Clinical Affairs
7000 Bee Caves Rd., Suite 250
Austin, Texas 78746

Re: K162656
Trade/Device Name: ESU-1 Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 21, 2016
Received: September 23, 2016

Dear Ms. Kumar:

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.

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" (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.

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,

Jennifer R. Stevenson -A

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)*
K162656

Device Name
ESU-1 Electrosurgical Generator

Indications for Use *(Describe)*
The ESU-1 Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

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 (K162656)

ESU-1 Electrosurgical Generator

510(k) Owner

TVA Medical, Inc.
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Austin, TX 78746

Official Correspondent

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Date Prepared: September 8, 2016

Subject Device Name

Trade Name	ESU-1 Electrosurgical Generator
Common or usual name	Electrosurgical Generator
Classification name	Electrosurgical Cutting and Coagulation Device and Accessories [21 CFR 878.4400; product code GEI]
Class	II
Classification Panel	General and Plastic Surgery (79)

Predicate Device

Bovie® IDS-310 Electrosurgical Generator [Bovie Medical Corporation; K134054]

Device Description

The ESU-1 Electrosurgical Generator is a high frequency isolated generator that utilizes electrical current via an assortment of surgical devices to cut and coagulate different types of tissue. The ESU-1 Electrosurgical Generator features cutting up to 300 watts with 2 cut modes, including "Cut T", a blend mode with 4 levels, 3 coagulation modes and 4 bipolar modes with Auto Bipolar option. "Cut T" mode is a new feature that includes a timing feature which automatically ceases RF activation after a user selectable period of time that can be altered between 0.1 and 3.0 seconds. The RF activation for Cut T mode is initially pre-set at 2 seconds (Note: if the operator changed these settings, the generator will power-up with the mode and setting in which the operator last activated the generator). The generator offers 2 monopolar headpiece outputs, monopolar foot controlled output, bipolar handpiece output, and bipolar foot controlled output. The generator has a return electrode sensing feature allows the user to use either a split or solid return electrode site. The pad-sensing feature allows the user to use either a split or solid return electrode.

The device consists of a generator and power cord and is packaged with a User's Guide in a cardboard shipping box with protective foam inserts. The main device components are a front panel containing the power button, wattage selection buttons, LED numeric display, alarm and return electrode indicator lights, and connector ports for accessories, a back panel consisting of footswitch ports, volume controls, a power cord outlet and fuse, and internal components (printed circuit boards, speakers, cabling).

Indications for Use

The ESU-1 Electrosurgical Generator [ESU-1] is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

Comparison of Indications for Use to Predicate Device

The ESU-1 has the same indications for use as the Bovie IDS-310.

Comparison of Technological Characteristics to Predicate Device

The ESU-1 has the following similarities to the Bovie IDS-310:

- Both devices have the same intended use/indications for use
- Each device is identical in size, weight and construction.
- Each device uses high frequency RF current to deliver a desired clinical effect.
- Each device offers monopolar and bipolar output modes.
- Each device offers the same waveforms, output frequencies and maximum output power for all monopolar modes.

- Each device offers the same waveforms, output frequencies and maximum output power for Micro, Standard and Bovie Bipolar modes.
- Each device offers the AutoBipolar Feature.
- Each device offers the same Return Electrode Monitoring System.
- Each device has the same chassis.
- Each device has the same interconnections, internal printed circuit boards and electrical components.
- Each device has the same rated duty cycle.

The RF output for both generators is identical and both generators have identical modes with the exception that the ESU-1 has a "Cut T" mode, which includes a timing feature which automatically ceases RF activation after a user selectable period of time that can be altered between 0.1 and 3.0 seconds. The RF activation for Cut T mode is initially pre-set at 2 seconds. The Cut T mode replaces the Cut II function on the IDS-310. The RF output for both generators is identical.

Performance testing

The software for the ESU-1 has been verified and validated based on its moderate level of concern. The ESU-1 complies with IEC60601-1 (third edition), IEC60601-2 (electromagnetic compatibility), and IEC60601-2-2 standard for the safety of electrosurgical equipment. Bench testing was performed to demonstrate that the generator met its design specifications. The testing consisted of Mechanical Verification Testing, Inspection Verification Testing, Electrical Verification Testing, Shipping Study, FPGA Validation for Main Board, FPGA Validation for Display Board and was conducted on the ESU-1 or devices representative of its design.

The results from these tests demonstrate that the technological characteristics and performance criteria of the ESU-1 are adequate for the intended use of the device and that the device can perform in a manner equivalent to devices currently on the market with the same intended use.

Sterilization

The ESU-1 Electrosurgical Generator is a non-sterile device.

Biocompatibility

The ESU-1 Electrosurgical Generator is not a patient contacting device.

Conclusion

The ESU-1 met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The ESU-1 is substantially equivalent to legally marketed predicate devices.