March 24, 2020

Megadyne Medical Products, Inc.
℅ Kweku Biney
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery LLC
4545 Creek Road
Cincinnati, Ohio 45242

Re: K193145
Trade/Device Name: Ethicon Megadyne Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 26, 2020
Received: February 27, 2020

Dear Kweku Biney:

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)*
K193145

Device Name
Ethicon Megadyne® Electrosurgical Generator

Indications for Use *(Describe)*
The Ethicon Megadyne® Electrosurgical Generator is intended as a general-purpose electrosurgical generator designed to produce radio frequency (RF) current for cutting and coagulation to be delivered to target tissue through an accessory electrode during open and laparoscopic surgical procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Company Megadyne Medical Products, Inc.
11506 South State St.
Draper, UT 84020

Contact Kweku Biney
Sr. Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-3135
Email: kbiney@its.jnj.com

Date Prepared
March 24, 2020

Device Name
Trade Name: Ethicon Megadyne Electrosurgical Generator
Common Name: Electrosurgical Cutting and Coagulating Instruments

Classification Name
• Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code GEI)

Regulatory Class
Class II

Predicate Device
Mega Power Electrosurgical Generator initially cleared under K050579 on March 24, 2005.

Device Description

The Ethicon Megadyne Electrosurgical Generator is a microprocessor controlled, isolated output, high frequency generator designed for use in cutting and coagulation of tissue. The generator has the ability to perform both monopolar cutting and coagulation and bipolar coagulation of tissue in a wide range of surgical applications.

Indications for Use

The Ethicon Megadyne Electrosurgical Generator is intended as a general-purpose electrosurgical generator designed to produce radio frequency (RF) current for cutting and coagulation to be delivered to target tissue through an accessory electrode during open and laparoscopic surgical procedures.

Comparison of Technological Characteristics with the predicate Device

The subject device is similar to the predicate device in design, intended use, energy delivery, materials, performance, safety, effectiveness, labeling and operating principle. Both the subject and predicate device use the same accessories except for the round bi-polar footswitch which is only compatible with the subject device.

Discussion of Differences

Both the subject and predicate share several features and characteristics. The major technological features that have been designed into the subject device are listed below.
New Features:
a. Soft COAG: Pressing the SOFT button places the generator in the SOFT Coag mode. The SOFT mode desiccates tissue at a relatively slower rate with deeper thermal penetration. SOFT mode is typically used with an uncoated electrode. SOFT Coag power delivery takes place at much lower impedance than other Coag modes.
b. GEM LOW: This is a new mode on the subject device and has half the voltage of the GEM high mode. GEM high is equivalent to the ACE Cut mode in the predicate device.
c. Auto-Bipolar: The auto Bipolar is a new activation method which senses tissue impedance between the bipolar electrodes and uses this information to auto start or stop the delivery of bipolar energy. The user can select a long (1 second), short (0.5 second), or no delay prior to the onset of energy delivery.

New Accessory Footswitch:
a. A new bipolar footswitch is being introduced with introduction of the new device. The footswitch is the same as the square bipolar footswitch shown in figure 3 in section 11. This is just an ergonomic change from square to round.

Summary Device Comparison Table

Device Characteristic	**Ethicon Megadyne Electrosurgical Generator (Subject)**	**MEGA Power Electrosurgical Generator (Predicate Device)**
Operating Low/High Mains Voltage (Domestic)	90 to 132 VAC@ 50/60Hz	Same
Operating Low/High Mains Voltage (international)	216 to 264 VAC @ 50/60 Hz	240 to 264 VAC @ 50/60 Hz
Operating Altitude/Pressure	700 hPa to 1060 hPa 25% at maximum power into rated load	Same
Maximum Operating Duty Cycle		

Device Characteristic	**Ethicon Megadyne Electrosurgical Generator (Subject)**	**MEGA Power Electrosurgical Generator (Predicate Device)**
Current Rating	Maximum Current Rating 5.0 Amps	Same
Power Consumption	Maximum Power Consumption <550 Watts	Same
Number of channels and type	There are two channels, one monopolar and the other is bipolar	Same
Power Display Settings	The power settings for Monopolar and Bipolar is displayed using LCD segment white numerical displays indicating the desired power setting in watts.	The power settings for Monopolar and Bipolar is displayed using independent segment green numerical displays indicating the desired power setting in watts.
Operating Conditions	Ambient temperature: +10°C (+50°F) to +40°C (+104°F) Relative humidity: 15% to 75% Non-condensing Atm. pressure: 700 hPa (10.2 psi) to 1060 hPa (15.37 psi)	Same
Storage Environment	Ambient temperature: -40°C (40°F) to +70°C (+158°F) Relative humidity: 10% to 95%, Condensing Atmospheric Pressure: 500 hPa (7.25 psi) to 1060 hPa (15.37 psi)	Ambient temperature: -40°C (-40°F) to +70°C (+158°F) Relative humidity: 10% to 95%, Condensing Atmospheric Pressure: 500 hPa (7.25 psi) to 1060 hPa (15.37 psi)
Equilibration Time	If the Ethicon Megadyne Generator has been stored at a temperature outside of its specified operating temperature range (10°C to 40°C) it should be allowed to reach room temperature before being used. This time is a minimum of one hour.	Same
Sterilization and Reprocessing	This product is sold and used as non-sterile	Same
Cleaning	The Ethicon Megadyne Generator is designed to be suitable for cleaning with damp cloth and mild cleaning solution or disinfectant.	Same
Operation and Service Manuals	An English language service manual is provided with each Ethicon Megadyne Generator. This service manual provides information about the installation and periodic safety checking required for the unit.	Same

Performance Data

The subject device has undergone testing to ensure that the design changes do not adversely affect the safety and performance of the device. A high-level summary of safety and performance testing that was completed for the device is documented below:

- **Biocompatibility testing**
  The Ethicon Megadyne Electrosurgical Generator device does not have any direct or indirect patient contacting components.

- **Electrical Safety and Electromagnetic Compatibility**
  To ensure electrical safety and electromagnetic compatibility of the subject device, testing was completed in compliance with IEC standard 60601-1 and IEC 60601-2-2 for electrical safety and IEC 60601-1-2 electromagnetic compatibility. IEC 60601-2-18 was also completed for capacitive coupling.

- **Sterilization/Shelf-Life**
  The subject device is packaged and shipped non-sterile.

- **Bench Testing**
  Thermal effects on tissue was evaluated for the subject device in comparison to the predicate as recommended by the FDA guidance. All Generator modes were evaluated with the corresponding devices to test for thermal effects on tissue. Ex-vivo harvested animal tissue from skeletal muscle, liver and kidney were used. These tissue types are selected to support the general soft tissue indication for the subject device. Thermal damage on tissue was measured through image analysis using open source image processing software. Testing was performed in triplicate at minimum, default and maximum power settings. Based on testing results, the thermal effect is not significantly different from what is measured from the predicate device.

- **Software Verification and Validation Testing**
  Software validation and verification was completed for the subject device following FDA's issued guidance on software, "*General Principles of Software Validation*" and "*Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*". The recommended documentation for a software with a Major level of concerns is provided in the software section of the submission.

- **Design Validation Testing**
  The design validation testing demonstrated the overall acceptability of the subject device setup and use for its intended users.

Conclusion

Based on the testing completed for Ethicon Megadyne Electrosurgical generator from a safety and performance perspective, the subject device is substantially equivalent to the predicate device as defined by all applicable FDA regulatory requirements and issued guidance documents.