January 21, 2022

Megadyne Medical Products, Inc.
% Rubina Dosani
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K213696
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: November 22, 2021
Received: November 23, 2021

Dear Rubina Dosani:

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, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213696

Device Name
ETHICON Megadyne Electrosurgical Generator

Indications for Use *(Describe)*
The Ethicon Megadyne Electrosurgical Generator (ESU) 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.

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510(k) Summary

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

Contact Rubina Dosani
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Ethicon Endo-Surgery, Inc.
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Date Prepared
November 22, 2021

Subject Device Name

Common Name:	Electrosurgical Cutting and Coagulating Instruments
Trade Name:	Ethicon Megadyne™ Electrosurgical Generator
Model:	OTTMEGEN
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Regulation:	21 CFR 878.4400
Regulatory Class:	Class II
Panel:	79, General and Plastic Surgery
Product Code:	GEI

Predicate Device

Common Name:	Electrosurgical Cutting and Coagulating Instruments
Trade Name:	Ethicon Megadyne™ Electrosurgical Generator
510(k) Number:	Initially cleared under K193145
Date of Clearance:	March 24, 2020
Model:	MEGEN1

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 (ESU) 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 has the same intended use and indications of use as the predicate device. The basic design, function, materials, performance, safety, effectiveness, and operating principle remain the same.

Differences

Both the subject and predicate devices share several features and characteristics. The major changes to the technological feature of the subject device compared to the predicate are as follows:

1. Maximum power output/setting of the monopolar mode has been decreased, except for the GEM mode.
2. Auto-bipolar option has been removed.
3. Single plate electrode accessories will not be compatible with this design of the subject device.

Summary Device Comparison Table

Device Characteristic	**Ethicon Megadyne Electrosurgical Generator (Subject Device)**	**Ethicon Megadyne Electrosurgical Generator (Predicate Device- K193145)**
Operating Low/High Mains Voltage	90 to 132 VAC@ 50/60Hz	Same
Operating Low/High Mains Voltage (international)	216 to 264 VAC @ 50/60 Hz	Same
Operating Altitude/Pressure	700 hPa to 1060 hPa	Same
Maximum Operating Duty Cycle	25% at maximum power into rated load	Same
Current Rating	Maximum Current Rating 5.0 Amps	Same
Power Consumption	Maximum Power Consumption <550 Watts	Same
Power Output	Maximum Power Output for all modes is 80W except GEM which is 150W	Maximum Power Output: Monopolar Cut mode is 300W Monopolar Coag mode is 120W Bipolar Mode is 80W

Device Characteristic	**Ethicon Megadyne Electrosurgical Generator (Subject Device)**	**Ethicon Megadyne Electrosurgical Generator (Predicate Device- K193145)**
Number of channels and type	There are two channels, monopolar and bipolar	Same
Auto Bipolar Feature	Not available	Available
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.	Same
Operating Conditions	Temperature Range: +10°C (+50°F) to +40°C (+104°F) Humidity Range: 15% to 75% Non-condensing Atmospheric Pressure: 700 hPa (10.2 psi) to 1060	Same
Storage Environment	Temperature Range: -40°C (40°F) to +70°C (+158°F) Humidity Range: 10% to 95%, Condensing Atmospheric Pressure: 500 hPa (7.25 psi) to 1060 hPa (15.37 psi)	Same
Equilibration Time	If the subject device 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	The device will be sold and used as non-sterile	Same
Cleaning	The subject device is designed to be suitable for cleaning with damp cloth and mild cleaning solution or disinfectant.	Same

Device Characteristic	Ethicon Megadyne Electrosurgical Generator (Subject Device)	Ethicon Megadyne Electrosurgical Generator (Predicate Device- K193145)
Operation and Service Manuals	An English language service manual will be provided with each device. 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 summary of safety and performance testing that was completed for the device is provided below:

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

- **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, IEC 60601-1-2 electromagnetic compatibility and IEC 60601-2-18 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. Thermal damage on tissue was measured through image analysis using open source image processing software. Testing was performed in triplicate at minimum, with default and maximum power settings. Based on testing results, the thermal effect for subject device 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" "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in

Medical Devices". The recommended documentation for a software with a "Major" level of concern is provided in the software section of the submission.

Conclusion

In conclusion, the performance testing demonstrates that the subject device performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

This submission does not include data from Clinical Studies.