January 17, 2025

Ethicon Endo-Surgery, LLC (a Johnson and Johnson company)
Lovelene Bangalon
Sr. Program Lead, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K243067
Trade/Device Name: The ETHICON™ Total Energy System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, HGI, LFL
Dated: September 27, 2024
Received: September 27, 2024

Dear Lovelene Bangalon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2025.01.17 12:49:55 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243067

Device Name
The ETHICON™ Total Energy System

Indications for Use *(Describe)*
The ETHICON™ Total Energy System is an electrosurgical generator that provides power to monopolar, bipolar, and ultrasonic surgical instruments. It is indicated for surgical procedures requiring cutting or coagulation of soft 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Sponsor: Ethicon Endo-Surgery, LLC
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Date Prepared:

January 15, 2025

Device and Classification Information:

Trade Name:	The ETHICON™ Total Energy System
Common Name:	Electrosurgical Cutting and Coagulation Instruments
Classification Regulation:	21 CFR 878.4400, 21 CFR 884.4120, and Unclassified
Classification Name:	Electrosurgical, cutting & coagulation & accessories
Product Code:	GEI, HGI, LFL
Device Class:	Class II
Panel:	79, General and Plastic Surgery

Device Description Summary:

The subject device, The ETHICON™ Total Energy System, is an electrosurgical generator that integrates Advanced Energy (Advanced Bipolar and Ultrasonic) and Core Monopolar and Bipolar energy modalities into one system, the Ethicon Total Energy System.

The subject device consists of two modules: the Communications Module (ETHCM and ETHUSC) and the Energy Module (ETHEM).

Atop the Energy Module is the Communications Module and the User Screen. The Communications Module contains the power button and speakers, connects to the User Screen, distributes power to the system, and provides external interfaces for other connectivity to external devices including Ethernet and USB.

One or two Energy Modules can be connected to the Communications Module. When two Energy Modules are connected, each Energy Module can independently power any of the energy modalities. This feature allows for simultaneous use of two surgical instruments in one system to support complex surgical procedures where two surgeons are operating on a patient at the same time.

The User Screen features a touch-operable graphical user interface (GUI) for system settings adjustment, user profile management, and alarm troubleshooting.

The ETHICON™ Total Energy System accessories include a cart for system transport, footswitches (single, double, round), and an output verification key. The cart provides a mobile platform with adjustable shelves and accessory storage. Additionally, the cart has custom features to create stability for the system including cut-outs on the top shelf for holding the rubber feet of a second module layers. Casters provide 360º mobility with locking tabs that lock to prevent unwanted cart movement.

Footswitches may be used to control power delivery to connected instruments, enabling surgeons to activate the energy output hands-free. The different footswitches can be used for various energy modalities and instruments. Up to four footswitches can be connected to the Communications Module of the Ethicon Total Energy System at the same time. The footswitches are assigned to the desired instrument port via the User Screen GUI.

Output Verification is a service mode of the system used to periodically confirm that the power outputs of each energy modality are within the required specifications. The Energy Output Verification Key is used by biomed/hospital facility servicing personnel to complete this process for annual maintenance on the Energy Module, with on-screen guidance to assist in this process.

The ETHICON™ Total Energy System is compatible with Ethicon HARMONIC™, Ethicon ENSEAL™, and Ethicon MEGADYNE™ monopolar and bipolar instruments.

Intended Use /Indications for Use:

The ETHICON™ Total Energy System is intended to supply energy to surgical devices.

The ETHICON™ Total Energy System is an electrosurgical generator that provides power to monopolar, bipolar, and ultrasonic surgical instruments. It is indicated for surgical procedures requiring cutting or coagulation of soft tissue.

The subject device has the same indications for use as the predicates.

Indications for Use Comparison:

Indications for use for the subject device are the same as the predicates.

Subject Device Indication:
The ETHICON™ Total Energy System is an electrosurgical generator that provides power to monopolar, bipolar, and ultrasonic surgical instruments. It is indicated for surgical procedures requiring cutting or coagulation of soft tissue.

Predicate Device Indications:

GENERATOR 11, GEN11: The Generator G11 provides radiofrequency power to drive ENSEAL electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive HARMONIC ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

ENSEAL and HARMONIC instruments, when used with the Generator G11, have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

MEGADYNE, MEGEN1: 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.

Technological Comparison:

The technological comparison of the subject device, The ETHICON™ Total Energy System, to the predicate devices, as per 21 CFR 807.92(a)(6), establishes substantial equivalence. The subject device integrates the functionalities of two predicates: The Generator 11 and MEGEN1. GEN11 provides radiofrequency capabilities to power electrosurgical instruments for cutting and sealing vessels, while MEGEN1 serves as a general-purpose electrosurgical generator designed to produce radiofrequency current for cutting and coagulation. The Ethicon Total Energy System combines these core and advanced features to offer a comprehensive solution for surgeons as it incorporates both functionalities into a single surgical generator system. The testing of these functionalities

demonstrates the capability of the subject device to meet and exceed the performance and safety benchmarks set by the predicate devices.

Based on the intended use and technological comparison, data supports that the subject device is substantially equivalent to the predicate devices in functionality, performance and intended use. The subject device combines the proven capabilities of GEN11 and MEGEN1 while offering additional features and benefits to meet the evolving needs of healthcare professionals. This combination of power functionalities into 1 single system enhances the subject device usability in surgical procedures.

Non-Clinical and/or Clinical Test Summary & Conclusions:

The nonclinical tests provided according to 21 CFR 807.92 include electrical characterization, algorithmic performance verification, functional testing and human factors testing. The subject device's performance was benchmarked against the predicate devices, demonstrating equivalent output, stability, and thermal spread control. Bench testing confirmed instrument vessel sealing and cutting capabilities when powered with the Subject Device. Human factors testing confirmed usability and safety in clinical settings. Pre-clinical testing of hemostasis, healing response and thermal effects indicated safe and effective operation of instruments powered by the subject device comparable to the predicate devices, establishing substantial equivalence.

The premarket submission did not rely on clinical testing. The subject device showed either equivalent or improved performance compared to the predicate devices and met all functional requirements of its features. It successfully met the acceptance criteria for bench testing, animal studies, usability, and electrical testing, demonstrating no new safety or effectiveness issues compared to the predicate.

Testing protocols conducted:

> **Bench Testing:** This included Electrical Safety testing per IEC 60601-1 standards, Electromagnetic Compatibility (EMC) testing as per IEC 60601-1-2 standards, thermal spread testing to evaluate thermal effects on tissue, and burst pressure testing to assess the strength of sealed vessels.
>
> **Animal Studies:** The *in vivo* studies focused on vessel and tissue transection capabilities, with assessments conducted during acute and chronic phases to evaluate both immediate and long-term performance.

Software and Cybersecurity:

The subject device, The ETHICON™ Total Energy System, includes software specifically designed to ensure precise energy delivery, enhance device usability, and support overall safety in clinical environments. The software validation activities were conducted in accordance with FDA guidance, specifically *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".* The software has been classified as Enhanced Documentation to reflect the detailed testing and evaluation performed.

Additionally, the validation process adhered to the *"General Principles of Software Validation: Guidance for Industry and FDA Staff"* FDA guidance, as well as the *"Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff"* ensuring that all aspects of the software lifecycle meet regulatory requirements.

To fulfill cybersecurity requirements, the FDA guidance *"Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions"* was followed. These measures ensure the software's integrity, reliability, and protection against unauthorized access. It is also important to note that wired foot switches included in this submission do not contain software.

Overall, the subject device has been shown to perform as intended, equivalent or better than the predicate devices.

Substantial Equivalence Comparison:

For purposes of the substantial equivalence comparisons, the following predicate device was selected:

Tradename	Product Code	Modalities Delivered	510(k) (Decision Date)
Ethicon Endo-Surgery Generator G11	GEN11	Ultrasonic Advanced Bipolar	K200841 (11 May 2020)
Ethicon Megadyne Electrosurgical Generator	MEGEN1	Monopolar/ Bipolar	K193145 (24 Mar 2020)