July 26, 2019

Megadyne Medical Products, Inc.
% Ryoji Sakai
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K191328
Trade/Device Name: Megadyne Foot Switch
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus For A Surgical Operating Room
Regulatory Class: Class II
Product Code: FYD
Dated: May 15, 2019
Received: May 16, 2019

Dear Ryoji Sakai:

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic 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)*

K191328

Device Name
Megadyne Foot Switch

Indications for Use *(Describe)*

The Megadyne Foot Switch is an accessory that is intended to interface with compatible smoke evacuation systems to control on/off inputs for manual operation.

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

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

Contact Ryoji Sakai
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-8586
Email: rsakai3@its.jnj.com

Date Prepared
July 17, 2019

Device Name
Trade Name: Megadyne Foot Switch
Common Name: Foot Switch

Classification Name
Air-handling apparatus for surgical operating room (21 CFR 878.5070, Product Code FYD)

Regulatory Class
Class II

Predicate Devices
IR Wireless Foot Switch cleared under K053510 on March 20, 2006

Device Description
The Megadyne Foot Switch is used with a compatible smoke evaluation system to control on/off inputs for manual operation.

Indications for Use

The Megadyne Foot Switch is an accessory that is intended to interface with compatible smoke evacuation systems to control on/off inputs for manual operation.

Technical Characteristics:

Comparison with The Predicate Device

Indications for Use	
Megadyne Foot Switch *(Subject device)*	**IR Wireless Foot Switch** *(Predicate device)*
The Megadyne Foot Switch is an accessory that is intended to interface with compatible smoke evacuation systems to control on/off inputs for manual operation.	The Linemaster wireless foot switch will be an accessory to and provide foot switch input control to any medical device that uses a switch closure (on/off), to activate said device.
Contraindications	
None	None

Device Comparison Table – Technology, and Performance Specifications

Characteristic/Specification	**Megadyne Foot Switch** *(Subject device)*	**IR Wireless Foot Switch** *(Predicate device)*
Sterility Method	Non-Sterile	Same
Connection method	Wired connection	Wireless connection
Compatible generator	Smoke evacuation system (Classification Name: Air-handling apparatus for surgical operating room)	Any class II medical device that uses a foot switch
Electrical Safety / Mechanical Safety	Tested and compliant with IEC 60601-1 and IEC 60601-1-2	Same
Biocompatibility Safety	Non-patient contact	Same
Radiation Safety	Non-radioactive	Same

The subject Megadyne Foot Switch and predicate IR Wireless Foot Switch control the same on/off inputs, however the Megadyne Foot Switch does not have the wireless capability. Electromagnetic Compatibility and Electrical Safety testing were performed to ensure that the different technological characteristics do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Testing

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Megadyne Foot Switch to comply with IEC 60601-1-2 for electromagnetic compatibility and IEC 60601-1 for electrical safety.

Durability of Marking Test

This footswitch meets the requirements for an IPX8 rating per IEC 60529 Ed. 2.2 and Legibility of the Label and Durability of the marking per IEC 60601-1 Ed. 3.1.

Mechanical Test Report

The footswitch meets the IEC 60601-1 Ed. 3.1 standard for Shipping, Storage and ME Test.

Clinical Studies

N/A

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Megadyne Foot Switch is as safe, as effective, and performs as well as or better than the legally marketed device.