June 26, 2020

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

Re: K200250
Trade/Device Name: Megadyne Smoke Evacuator
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 14, 2020
Received: May 18, 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,

Christopher K. Dugard, M.S.
Assistant Director (acting)
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

# 510(k) Summary -- K200250

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

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

**Date Prepared**
June 25, 2020

**Device Name**
Trade Name: Megadyne Smoke Evacuator
Common Name: Smoke Evacuation System

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

**Regulatory Class**
Class II

**Predicate Devices**
Crystal Vision cleared under K163659 on October 30, 2017

**Device Description**
The Megadyne Smoke Evacuator is designed to provide smoke evacuation in open and Laparoscopic procedures for the removal of surgical smoke. Using a scroll pump and 4 stages of filtration, the Megadyne Smoke Evacuator is designed to evacuate surgical smoke both quietly and effectively. An intuitive front panel design allows users to customize both the rate of suction FLOW and the length of RUN TIME after the active electrode is deactivated. Push button selections for OPEN, LAP (laparoscopic), and MANUAL modes are also clearly marked and easily accessible. The Megadyne smoke evacuator provides evacuation of smoke plume via a smoke evacuation device and tubing (e.g. E-Z Clear Smoke Evacuation Electrosurgical Pencil under K141587 on February 18, 2015) connected to the face of the Filter.

**Indications for Use**

| |
|---|
| The Megadyne Smoke Evacuator with accessories is intended to remove smoke created in surgical procedures at the surgical site. |

**Technological Characteristics**

The Megadyne Smoke Evacuator is a microprocessor controlled, smoke evacuation and filtration device. It has push button controls for flow, time and mode. It can be used in open or laparoscopic surgery. It has a replaceable filter to remove smoke particulates. This filter contains a feature to keep track of filter life. An optional accessory fluid trap is available to trap fluids from surgery that can decrease filter function. In addition to the power cord, Megadyne Connect cable is supplied. This cable attaches to an ESU (Electrosurgical Unit) or other advanced energy hardware allowing the Megadyne Smoke Evacuator to activate when the ESU (Electrosurgical Unit) activates. As an alternative method for activation, Megadyne RF sensor is available for use.

| **Device & Predicate Device(s):** | K200250 | K163659 |
|---|---|---|
| General Device Characteristics | | |
| Indications for Use | The Megadyne Smoke Evacuator with accessories is intended to remove smoke created in surgical procedures at the surgical site. | The Crystal Vision Smoke Evacuator System with Accessories is intended to remove smoke created in surgical procedures. |
| Sterility Method | Non-Sterile | Same |
| Voltage Input | 100-240V, 50/60 Hz | Same |
| Maximum Flow Rates | Open Mode: 118 LPM<br>Lap Mode: 41 LPM | Open Mode: 90 LPM<br>Lap Mode: 18 LPM |
| Time Control | Open Mode: Adjustable 3 to 30 Seconds Lap Mode: Adjustable 2 to 10 seconds | Adjustable from 2 to 35 seconds |
| Filter specification | Filter Efficiency of 99.999% at 0.1 to 0.2 microns | Same |
| Filter life | Lap Mode: 35 hrs<br>Open Mode: 26 hrs | Multiple use: Change when CHANGE FILTER illuminates on front panel (no filter life data) |
| Accessories | Tubing1) | Tubing |
| | Fluid Trap | The ULPA Filter & Water Trap |
| | Filter | Charcoal Output Filter |
| | Connect Cables | NA2) |
| | RF sensor | Sensor |
| | NA | Footswitch |
| Materials of construction | Powered-Coated Aluminum Housing, ABS-PVC Thermal | Powered-Coated Aluminum Housing, ABS-PVC Thermal |

| | | |
|---|---|---|
| (Non-patient contact) | Plastic, Insulation, Glass micro fiber filter media, granular activated carbon | Plastic, Insulation, Glass micro fiber filter media, granular activated carbon |
| Electrical Safety | Tested and compliant with IEC 60601-1 and IEC 60601-1-2 | Same |
| Mechanical Safety | Tested and compliant with IEC 60601-1 and IEC 60601-1-2 | Same |
| Biocompatibility Safety | Non-patient contact | Same |
| Thermal Safety | Operation of device does not result in harmful temperatures. Tested and compliant with IEC 60601-1 and IEC 60601-1-2 | Same |
| Radiation Safety | Non-radioactive | Same |

**Non-clinical Tests**

Non-clinical testing was conducted to demonstrate that the Megadyne Smoke Evacuator with its accessories functions as intended. Below is a summary of testing conducted on the subject device.

| **Title of Test** | **Purpose of Test** | **Acceptance Criterial** | **Results** |
|---|---|---|---|
| Electrical Safety Testing | Evaluate Electrical Safety | Fulfil the requirements of IEC 60601-1: 2012 reprint as applicable | Passed |
| Electromagnetic Compatibility | Evaluate Electromagnetic compatibility | Fulfil the requirements of 60601-1-2 4$^{th}$ edition as applicable | Passed |
| Software Validation | Evaluate device software | All test cases shall pass or deviations explained as to why it is acceptable | Passed |
| Flow Rate Testing | Evaluate flow rate against design requirement | The flow rates at each FLOW setting in LAP mode of the MESE1 units are within the defined tolerances. | Passed |

| Title of Test | Purpose of Test | Acceptance Criterial | Results |
|---|---|---|---|
| Filter life Testing | Evaluate filter life against design requirement | The filter life testing shall be successful if time-based filter requirement is met | Passed |
| Design Validation | Objective evidence that the subject device meets the needs of the user | There shall be no pattern of use error, close calls or difficulty using the device | Passed |
| Tissue Effects in Laparoscopic procedures | Tissue effects of unintended high vacuum | Effects on tissue shall be minimal | Passed |

***Conclusion***

The conclusions drawn from the nonclinical testing of Megadyne Smoke Evacuator demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.