May 27, 2020

Ethicon Endo-Surgery
% Emily Nesbitt
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Rd
Cincinnati, Ohio 45242

Re: K200253
Trade/Device Name: Megadyne Telescoping Smoke Evacuation Pencil
Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector
Megadyne Telescoping Soft Tissue Dissector
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 31, 2020
Received: March 31, 2020

Dear Emily Nesbitt:

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)*
K200253

Device Name
EGADYNE™ Telescoping Soft Tissue Dissector, MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector and MEGADYNE Telescoping Smoke Evacuation Pencil

Indications for Use *(Describe)*

MEGADYNE™ Telescoping Soft Tissue Dissectors are monopolar devices designed for general electrosurgical applications including cutting and coagulation (coag). The devices conduct an electrosurgical current from an electrosurgical unit (ESU) and deliver it to the target tissue to achieve the desired surgical effect. The electrosurgical active electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the ESU to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. The electrosurgical active electrodes have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the MEGADYNE™ ESU's Advanced Cutting Effect (ACE) mode or the MEGADYNE™ ESU's Geometric Electron Modulation (GEM) mode.

MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissectors and MEGADYNE Telescoping Smoke Evacuation Pencils are monopolar devices designed for general electrosurgical applications including cutting and coagulation (coag) and for removing smoke generated by electrosurgery when used in conjunction with a smoke evacuation system. The devices conduct an electrosurgical current from an electrosurgical unit (ESU) and deliver it to the target tissue to achieve the desired surgical effect. The [Megadyne PTFE coated] electrosurgical active electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the ESU to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

The [MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector] electrosurgical active electrodes have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the MEGADYNE™ ESU's Advanced Cutting Effect (ACE) mode or the MEGADYNE™ ESU's Geometric Electron Modulation (GEM) mode.

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 S. State Street
Draper, UT 84020

Contact Emily Nesbitt
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery LLC and Megadyne Medical Products, Inc
Telephone: 513.337.1546
Email: enesbitt@its.jnj.com

Date Prepared: January 24, 2020

Trade Names:	Megadyne™ Telescoping Smoke Evacuation Pencils, Megadyne™ Telescoping Smoke Evacuation Soft Tissue Dissectors Megadyne™ Telescoping Soft Tissue Dissectors
Common Name	Electrosurgical Cutting and Coagulating Instrument
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Panel:	General and Plastic Surgery
Predicate Device:	K141587, ZIP PEN Smoke Evacuation Electrosurgical Pencils
Reference Device:	K081791, E-Z Clean Electrosurgical Electrodes

Device Description

The Megadyne™ Telescoping Soft Tissue Dissectors, Megadyne Telescoping Smoke Evacuation Pencils, and Megadyne™ Telescoping Smoke Evacuation Soft Tissue Dissectors are sterile, single-use, hand-held electrosurgical pencils. These monopolar devices are designed for general electrosurgical applications including cutting and coagulation of tissue. The Megadyne™ Telescoping Smoke Evacuation Pencil and Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector offer an additional design feature to remove smoke generated by electrosurgery, when used in conjunction with a smoke evacuation system.

The printed circuit board in the device and electrical cable provide the means for powering the devices. The device dome switch, with over-molded buttons, operate the cut and coagulate functions of the device. The yellow button controls the cut function of the device, the blue button controls the coagulate function of the device.

Within the pencil nozzle, there is a collet that holds the electrode in place. The Megadyne™ Telescoping Smoke Evacuation Pencil, and Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector have a clear tube connected to the nozzle, which provides a route to remove captured electrosurgical smoke. The tubing terminates at a connector on the smoke evacuation system.

The devices are available in 10 ft. cord/tubing and 15 ft. cord/tubing. The packaged device includes:

- The pencil or handle with the attached power cord,
- A holster which may be used to hold the device when it is not in use during a surgical procedure, and
- An electrode, which may be exchanged by the user as needed. Additional electrodes are distributed separately.

Subject Device Compatible Electrodes

Product	Electrode	Smoke Function	Smoke Connector
Megadyne Telescoping Smoke Evacuation Pencils	E-Z Clean Electrode – K08179; cleared 21-Oct-2008	Yes	Universal
Megadyne Telescoping Smoke Evacuation Soft Tissue Dissectors	ACE Blade Electrode -K081791; cleared 21-Oct-2008	Yes	Universal
Megadyne Telescoping Soft Tissue Dissectors	ACE Blade Electrode -K081791; cleared 21-Oct-2008	No	N/A

Indications for Use

MEGADYNE™ Telescoping Soft Tissue Dissectors are monopolar devices designed for general electrosurgical applications including cutting and coagulation (coag). The devices conduct an electrosurgical current from an electrosurgical unit (ESU) and deliver it to the target tissue to achieve the desired surgical effect. The electrosurgical active electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the ESU to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

The electrosurgical active electrodes have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the MEGADYNE™ ESU's Advanced Cutting Effect (ACE) mode or the MEGADYNE™ ESU's Geometric Electron Modulation (GEM) mode.

MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissectors and MEGADYNE Telescoping Smoke Evacuation Pencils are monopolar devices designed for general electrosurgical applications including cutting and coagulation (coag) and for removing smoke generated by electrosurgery when used in conjunction with a smoke evacuation system. The devices conduct an electrosurgical current from an electrosurgical unit (ESU) and deliver it to the target tissue to achieve the desired surgical effect. The Megadyne PTFE coated electrosurgical active electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the ESU to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

The MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector electrosurgical active electrodes have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the MEGADYNE™ ESU's Advanced Cutting Effect (ACE) mode or the MEGADYNE™ ESU's Geometric Electron Modulation (GEM) mode.

Summary of Similarities and Differences in Technological Characteristics

The Megadyne Telescoping Smoke Evacuation Pencils, Megadyne Telescoping Smoke Evacuation Soft Tissue Dissectors and Megadyne Telescoping Soft Tissue Dissectors are the same as the Predicate Device in the technological principle because they are all monopolar electrosurgical pencils used in general electrosurgical applications including cutting and coagulation of tissue. At a high level, the Subject and Predicate Devices are based on the following same technological elements:

- Supplied power by an external generator.
- Devices have the same rated voltage 5.5 kV peak.
- Same general steps for use.
- Operation function switches, used to switch between "CUT" and "COAG"
- Polycarbonate Nozzle and design
- Optional use of smoke evacuation system, on the Megadyne Telescoping Smoke Evacuation Pencil and Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector
- Provided Sterile, Sterility Assurance Level SAL 10^{-6}

The Subject Devices have a telescoping end-effector, whereas the Predicate Devices do not have a telescoping end-effector feature. The Subject Devices have a new collet material to hold the electrode. The only difference between the Predicate and Subject conductive pathway is the collet material. Although different, the resistance difference is negligible compared to the anticipated resistances observed in electrosurgical use. The Subject Devices include either an ACE Electrode or an EZ Clean Electrode. Two of the six Subject Devices, the Megadyne™ Telescoping Soft Tissue Dissector, does not include the smoke evacuation feature to provide a non-smoke evacuation options to the surgeon, whereas the Predicate Devices have the smoke evacuation feature.

Performance Data

Bench performance including button cycling , device continuity, leakage current, fluid ingress, electrode extraction and retention, tube extension force, tube bend, biocompatibility, electrical safety, high frequency dielectric withstand, mains frequency dielectric withstand, button force, holster puncture force, thermal transfer of heat, summative usability validation, thermal spread of the electrode, electromagnetic compatibility, stability, and package evaluations were conducted to demonstrate that the Subject Devices, Megadyne™ Telescoping Smoke Evacuation Pencils, Megadyne™ Telescoping Smoke Evacuation Soft Tissue Dissectors and Megadyne™ Telescoping Soft Tissue Dissectors, perform as intended and are substantially equivalent to the Predicate Devices. This premarket submission did not rely on the assessment of animal performance data to demonstrate substantial equivalence.

<u>Clinical</u>

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Biocompatibility

Biocompatibility assessments including pyrogenicity, cytotoxicity, sensitization, irritation/intracutaneous reactivity and acute systemic toxicity were completed on the Subject Device.

Consensus Standards

All components of the Megadyne™ Telescoping Soft Tissue Dissectors, Megadyne™ Telescoping Smoke Evacuation Pencils, and Megadyne™ Telescoping Smoke Evacuation Soft Tissue Dissectors are in accordance with the following standards:

ANSVA/AAMI/ISO 11137-2:2016, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

IEC 60601-1-2 ed 4 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

ANSI AAMI 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint). Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD). FDA Recognition 19-4

IEC 60601-2-2: 2017-03 (for use in conjunction with IEC 60601-1:2005, COR1:2006, COR 2:2007, AMD1:2012 or IEC 60601-1:2012). Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories FDA Recognition 6-389.

Conclusion

The device evaluations demonstrate that the Megadyne Telescoping Smoke Evacuation Pencils, Megadyne Telescoping Smoke Evacuation Soft Tissue Dissectors, and Megadyne Telescoping Soft Tissue Dissectors are substantially equivalent to the Predicate Devices and modifications do not alter the intended use or introduce new issues of safety of effectiveness.