July 12, 2024

Megadyne Medical Products, Inc.
Brian Godwin
Associate Director, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K23364
Trade/Device Name: Megadyne Patient Return Electrode Pad - Universal Dual (model 0846),
Megadyne Patient Return Electrode Pad - Universal Plus (model 0847),
Megadyne Patient Return Electrode Pad - Universal Dual Plus (model 0848)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 5, 2024
Received: June 5, 2024

Dear Brian Godwin:

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.

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: 2024.07.12 07:15:22 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233644

Device Name

Megadyne Patient Return Electrode Pad (Universal Dual (model 0846));
Megadyne Patient Return Electrode Pad (Universal Plus (model 0847));
Megadyne Patient Return Electrode Pad (Universal Plus Dual (model 0848));
Megadyne Patient Return Electrode Pad (Universal (model 0845))

Indications for Use *(Describe)*

This device is designed to be used whenever monopolar electrosurgery is indicated. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units (ESU), or generators.

Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators. The device is not intended for RF ablation.

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

I. SUBMITTER

Company: Megadyne Medical Products, Inc
4545 Creek Rd
Cincinnati, OH 45242

Establishment Registration: 1721194

Contact: Brian Godwin
Associate Director, Regulatory Affairs
Phone: 513-337-3623
Email: bgodwin@its.jnj.com

Date Prepared: 13 Nov 2023

II. SUBJECT DEVICES

Trade Name:

- Megadyne Mega Soft Patient Return Electrode Universal (model 0845)
- Megadyne Mega Soft Patient Return Electrode Universal Dual (model 0846)
- Megadyne Mega Soft Patient Return Electrode Universal Plus (model 0847)
- Megadyne Mega Soft Patient Return Electrode Universal Plus Dual (model 0848)

Common or Usual Name: Device, electrosurgical & coagulation and accessories
Classification Name: Electrosurgical cutting & coagulation device & accessories
Classification Number: 21 CFR 878.4400
Regulatory Class: II
Product Code: GEI

III. PREDICATE DEVICES

Predicate Device 510(k) Number (Clearance Date)	**Predicate Device Name**	**Model**
K133726 (24 Jan 2014)	Mega Soft Universal Patient Return Electrode	0845

This predicate has not been subjected to a recall related to these design modifications.

IV. REFERENCE DEVICES

Reference Device 510(k) Number (Clearance Date)	**Reference Device Name**	**Model**
K031285 (19 May 2003)	Mega Soft Dual Cord Patient Return Electrode	0835
K080741 (16 Dec 2008)	Mega Soft Universal Patient Return Electrode	0840
K183148 (05 Feb 2020)	OKLand Patient Return Electrode Pad	AHD-001, AHD-003 AHD-004, AHD-005 AHD-006

There is no change in the base materials or technological characteristics between the subject Megadyne Mega Soft Patient Return Electrode (models 0845, 0846, 0847, 0848) and the predicate devices Mega Soft Universal Patient Return Electrode model 0845 which was cleared under K133726 on 24 Jan 2014.

V. DEVICE DESCRIPTION

The device is intended to be used as a 24-month reusable patient return electrode for patients age 12 years and older. The Universal (model 0845) and Universal Plus (model 0847) have a single cord that connects to one generator. The Universal Dual (model 0846) and Universal Plus Dual (model 0848) have two cords that can connect to one or two generators.

The Mega Soft Universal Patient Return Electrodes (ie, Mega Soft) are constructed of a layer of conductive material strain-relieved between an insulative polymer gel, and sealed between two layers of a thermal polyurethane plastic film. The thermal polyurethane plastic film and the contained polymer gel enveloping the conductive material is compressable but does not laterally move under pressure. The polymer acts as a dielectric protection and is encapsulated by a layer of urethane film. The dielectric protection remains between the thermal polyurethane plastic film and the conductive layer irrespective of pressure.

A two-conductor cable connects the conductive layer of the device to a two-conductor DetachaCable™. The DetachaCable is connected to a standard monopolar ESU. The DetachaCable is available in a variety of configurations and lengths, designed to be compatible with the various compatible generators available on the market and was cleared under K080741 on 16 December 2008.

VI. INDICATIONS FOR USE

This device is designed to be used whenever monopolar electrosurgery is indicated. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units (ESU), or generators.

Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators. The device is not intended for RF ablation.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological Characteristics

The Megadyne Mega Soft Patient Return Electrodes (subject devices) have the identical technological characteristics as the predicate device Mega Soft Universal Patient Return Electrode. Both the subject and predicate devices are intended to pass current from the active electrode through the patient's body to the patient return electrode and back to the generator to complete the circuit.

Similarities with the subject devices compared to the predicate devices cleared under K133726 are listed below.

- Indications
- Materials
- Operational principles
- Packaging
- Shelf-Life

The following differences exist between the subject and predicate device, (dependent upon model):

- Intended population
- Pad thickness
- Dual cord (model 0846 and 0848)
- Model number/tradename

VIII. PERFORMANCE DATA

Bench Performance

Bench performance testing was conducted to demonstrate equivalency of the subject devices to the predicate devices. The following parameters were evaluated:

- Electrical resistance
- Wear and use
- Cleaning and handling
- Compliance with IEC 60601-1, IEC 60601-1-2
- Compliance with IEC 60601-2-2

Animal Testing

Acute animal studies were conducted that evaluated the performance of the Mega Soft Universal Patient Return Electrode in simulated surgical procedures.

- Compliance with IEC 60601-2-2 5th Ed
- Pad orientation

IX. CONCLUSION

The testing criteria demonstrates that the following subject devices perform and are substantially equivalent to the predicate device, Mega Soft Universal Patient Return Electrode (K133726, model 0845).

- Megadyne Mega Soft Patient Return Electrode Universal (model 0845)
- Megadyne Mega Soft Patient Return Electrode Universal Dual (model 0846)
- Megadyne Mega Soft Patient Return Electrode Universal Plus (model 0847)
- Megadyne Mega Soft Patient Return Electrode Universal Plus Dual (model 0848)

The design requirements raise no new questions of safety and effectiveness.