December 19, 2024

Medline Industries, LP
Jin Ok
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

RE: K242370
Trade/Device Name: Medline Microdissection Needle (4 cm) (140936 (ESE104A)); Medline Microdissection Needle (3 cm) (140937 (ESE103A))
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 4, 2024
Received: December 4, 2024

Dear Jin Ok:

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: 2024.12.19 07:54:35 -05'00'

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.

510(k) Number *(if known)*
K242370

Device Name
Medline Microdissection Needle (4cm) (140936 (ESE104A));
Medline Microdissection Needle (3cm) (140937 (ESE103A))

Indications for Use *(Describe)*
The Medline Microdissection Needle is a monopolar electrosurgical instrument used for precision soft tissue dissection. It is a single-use device intended for cutting, dissecting, and cauterizing soft tissue. The Medline Microdissection Needle is not intended for use in the central nervous system or in the central circulatory system.

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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Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

510(k) SUMMARY
[AS REQUIRED BY 21 CFR 807.92]

Submitter
Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person
Jin Ok, Regulatory Affairs Specialist
Phone: 224-931-7350
Email: jok@medline.com

Summary Preparation Date
December 18, 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Microdissection Needle
Classification Name: Electrosurgical cutting and coagulation device and accessories
Product Code: GEI
Classification Panel: General and Plastic Surgery
Regulatory Class: Class II
Regulation Number: 21 CFR 878.4400

Predicate Device
Stryker Leibinger Colorado MicroDissection Needle®
K033232

Device Description
The Medline Microdissection Needle is a sterile, active electrode that is also referred to as a needle. It is designed for precision cutting, dissecting, and cauterization. The device is comprised of stainless steel, tungsten, and polyolefin heat shrink and will be offered in two different lengths, 4 cm (140936/ESE104A) and 3 cm (140937/ESE103A). The Medline Microdissection Needle is intended for connection with multiple brands of standard cautery pencils, including 510(k)-cleared Medline Cautery Pencil (K190643).

Indications for Use

The Medline Microdissection Needle is a monopolar electrosurgical instrument used for precision soft tissue dissection. It is a single-use device intended for cutting, dissecting, and cauterizing soft tissue. The Medline Microdissection Needle is not intended for use in the central nervous system or in the central circulatory system.

Summary of Technological Characteristics

Table 1 summarizes the technological characteristics of the Medline Microdissection Needle as compared to the predicate device.

Table 1 – Comparison of proposed and predicate device

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Microdissection Needle	Stryker Colorado Microdissection Needle®	N/A
510(k) Reference	K242370	K033232	N/A
Manufacturer	Applied Medical Coatings	Stryker	N/A
Product Code	GEI	GEI	Same
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	Same
Classification Name	Electrosurgical Cutting & Coagulation & Accessories	Electrosurgical Cutting & Coagulation & Accessories	Same
Regulation Number	878.4400	878.4400	Same
Indication for Use	The Medline Microdissection Needle is a monopolar electrosurgical instrument used for precision soft tissue dissection. It is a single-use device intended for cutting, dissecting, and cauterizing soft tissue. The Medline Microdissection Needle is not intended for use in the central nervous system or in the central circulatory system.	The Colorado MicroDissection Needle® is a monopolar electrosurgical instrument used for precision soft tissue dissection. Including but not limited to tonsillectomy and blepharoplasty. It is a single-use device intended for cutting, dissecting, and cauterizing soft tissue. The Colorado Microdissection Needle is not intended for use in the central nervous system or in the central circulatory system.	Same – Both devices are for precision soft tissue dissection and for cutting, dissecting, and cauterizing soft tissues.

Materials	Tube – Stainless Steel Tip/Needle – Tungsten Insulation – Polyolefin heat shrink Tip Protector – PVC Compound Tip Protector Colorant – Ethylene Vinyl Acetate	Tube – Stainless Steel Tip/Needle – Tungsten Insulation – Polyolefin (latex free) Non-stick coating – Isolation PTFE	Similar: Minor differences in materials of construction are addressed via biological safety testing per ISO 10993-1 and functional testing. The differences do not alter the safety and effectiveness of the product
Design Features	The Medline Microdissection Needle is designed with an ultra-sharp (5 µm) tungsten needle that transfers current from the electrosurgical generator to a very small surface area of tissue	The Stryker Colorado Microdissection Needle® is designed with an ultra-sharp (5 µm) needle that transfers current from the electrosurgical generator to a very small surface area of tissue. The device has PTFE coating on the tip to reduce eschar build up	Similar: Functional testing, including thermal zone damage testing and tip/pencil compatibility testing on the subject device demonstrate the differences do not alter the safety and effectiveness of the product
Active Accessory	Compatible with a variety of standard monopolar electrosurgical hand pieces	Compatible with a variety of standard monopolar electrosurgical hand pieces	Same
Single Use vs. Reusable	Single-Use	Single-Use	Same
Sterile vs. Non-Sterile	Sterile (EO)	Sterile (EO)	Same
OTC vs Rx	Rx only	Rx only	Same
Shelf Life	3 years	5 years	Different: Shelf-life testing supports the proposed expiration date through evaluation of the packaging integrity for maintaining device sterility and/or evaluation of any changes to device performance or functionality
Physical Dimensions	Device Length:	Device Length: 20 mm - 200 mm Outer Shaft Diameter: 2.4 mm	Similar: Functional testing, including thermal zone

	• ESE103A: 51.75 ± 1.78 mm • ESE104A: 61.75 ± 1.78 mm Outer Shaft Diameter: 2.36 ± 0.1 mm		damage testing and tip/pencil compatibility, was performed on the subject device to ensure the differences do not alter the safety and effectiveness of the product
Connector Type	Stainless Steel Tube	Stainless Steel Tube	Same
Performance Specifications	Rated Supply Voltage: 4000Vpeak Max Power Output: 30 watts	Rated Supply Voltage: 5400 V Max Power Output: 50 watts	Different: Functional testing, including thermal zone damage testing and IEC 60601-2-2 was performed on the subject device to ensure the differences do not alter the safety and effectiveness of the product
Compatibility	IFU Statement: Before beginning the procedure, verify the compatibility of all instruments and accessories ALWAYS use the device only with monopolar electrosurgical generators and accessories that have been tested to and complies with IEC 60601 and EN 60601 standards. The active electrode is compatible with any active handle that has the same or lower rated accessory voltage and complies with the IEC 60601-2-2 standard given proper and secure fit.	IFU Statement: Use the Colorado MicroDissection Needle only with regulatory cleared and approved generators compatible with monopolar electrosurgical devices. The needle fits most cautery handpieces with a standard 2.4 mm or 1.6 mm shaft	Similar

Summary of Non-Clinical Testing

Biocompatibility Testing

The biological evaluation for Medline Microdissection Needle was conducted in accordance with ANSI/AAMI/ISO 10993-1 *"Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"* as recognized by FDA. Medline Microdissection Needle is categorized as an externally communicating device in contact with tissue/bone/dentin for a limited duration (less than 24hrs). Specific biocompatibility tests were selected under the guidance of ISO 10993-1 Annex A:

- ISO 10993-5: Cytotoxicity
- ISO 10993-10: Skin Sensitization
- ISO 10993-10: Skin Irritation
- ISO 10993-11: Acute Systemic Toxicity
- ISO 10993-11: Material Mediated Pyrogenicity

Performance Testing (Bench)

Non-clinical performance testing was completed on the Medline Microdissection Needle to demonstrate substantial equivalence to the predicate device as well as to support the safety and effectiveness of the subject device in accordance with the relevant test methods described below:

- Thermal Damage Zone Testing
- Tip/Pencil Compatibility
- Appearance
- Dimensional Measurements
- Compression Test

Electrical Safety and Electromagnetic Compatibility

Electrical safety and EMC testing were completed on the Medline Microdissection Needle in accordance with 60601 series of standards listed below:

- AAMI/ANSI ES 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

- IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests*

- IEC 60601-2-2 *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*

Performance Testing (Animal)
This section does not apply. No animal testing was performed.

Performance Testing (Clinical)
This section does not apply. No clinical testing was performed.

Stability (Shelf Life)
The Medline Microdissection Needle has a 3-year expiration date. In accordance with ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, aging studies have been conducted to verify the physical and mechanical properties of the device to ensure it will perform adequately and consistently during the proposed shelf life and does not degrade over time.

Medline Microdissection Needles are packaged in a Peelmaster Poly/Tyvek pouch. The pouch has a 5-year shelf life and is validated for performance in accordance with ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes.* A packaging description, including how the pouch has maintained the device's sterility, a description of the package integrity test methods, and a summary of the package integrity test results have been completed in accordance with ISO 11607-1.

Sterilization
Medline Microdissection Needle will be supplied as a sterile device, sterilized by ethylene oxide gas to a sterility assurance level (SAL) of $1x10^{-6}$. The sterilization validation for the Microdissection Needle complies with the requirements of ISO 11135 *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.*

- Ethylene oxide residual was evaluated in accordance with ANSI/AAMI/ISO 10993-7, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.*

- Bioburden testing was conducted in accordance with ISO 11737-1 *Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products.*

- Bacterial Endotoxin LAL Validation was conducted in accordance with ANSI/AAMI ST 72 *Bacterial endotoxins- Test methods, routine monitoring, and alternatives to batch testing* and USP <85>, *Bacterial Endotoxins*

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Medline Industries, LP concludes that the Medline Microdissection Needle is as safe and effective as the predicate device Stryker Leibinger Colorado MicroDissection Needle® based on the similarities in the intended use, indications for use, mechanism of action, as well as the functions and specifications.