



April 23, 2024

Microline Surgical, Inc.
Scott Marchand Davis
Director, QA/RA
50 Dunham Road, Suite 1500
Beverly, Massachusetts 01915

Re: K234147

Trade/Device Name: ReNew XR Handpiece, 25cm, with Bariatric Markings (3943M); ReNew XR Handpiece, 34cm, with Bariatric Markings (3941M); ReNew XR Handpiece, 42cm, with Bariatric Markings (3942M); ReNew XR Handpiece, Ratcheted, 25cm, with Bariatric Markings (3946M); ReNew XR Handpiece, Ratcheted, 34cm, with Bariatric Markings (3944M); ReNew XR Handpiece, Ratcheted, 42cm, with Bariatric Markings (3945M)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories

Regulatory Class: Class II

Product Code: GEI

Dated: March 11, 2024

Received: March 27, 2024

Dear Scott Marchand Davis:

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,

Mark Digitally signed
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Date: 2024.04.23
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Mark Trumbore, 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

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

Submission Number (if known)

Device Name

ReNew XR Handpiece, 25cm, with Reference Markings (3943M);
ReNew XR Handpiece, 34cm, with Reference Markings (3941M);
ReNew XR Handpiece, 42cm, with Reference Markings (3942M);
ReNew XR Handpiece, Ratcheted, 25cm, with Reference Markings (3946M);
ReNew XR Handpiece, Ratcheted, 34cm, with Reference Markings (3944M);
ReNew XR Handpiece, Ratcheted, 42cm, with Reference Markings (3945M)

Indications for Use (Describe)

The ReNew XR Handpieces and tips are indicated for cutting, grasping, dissecting, and coagulation of tissue in endoscopic and laparoscopic procedures.
The ReNew XR Handpiece is also indicated for reference length measurement of tissue during endoscopic and laparoscopic surgical procedures.

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

Prepared on: 2024-04-22

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Microline Surgical, Inc.
Applicant Address	50 Dunham Rd, Suite 1500 Beverly MA 01915 United States
Applicant Contact Telephone	(978)922-9810
Applicant Contact	Mr. Scott Marchand Davis
Applicant Contact Email	smarchanddavis@microlinesurgical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	ReNew XR Handpiece, 25cm, with Reference Markings (3943M); ReNew XR Handpiece, 34cm, with Reference Markings (3941M); ReNew XR Handpiece, 42cm, with Reference Markings (3942M); ReNew XR Handpiece, Ratcheted, 25cm, with Reference Markings (3946M); ReNew XR Handpiece, Ratcheted, 34cm, with Reference Markings (3944M); ReNew XR Handpiece, Ratcheted, 42cm, with Reference Markings (3945M)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code	GEI

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201884	ReNew XR Handpiece	GEI

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The ReNew XR Handpiece with Reference Markings is a reusable laparoscopic surgical device used, in combination with legally marketed interchangeable end effectors, such as scissors, graspers, and dissectors (all of which are outside of the scope of this submission). It is indicated for cutting, grasping, dissecting, and coagulation of tissue in endoscopic and laparoscopic procedures and it is also indicated for reference length measurement of tissue during endoscopic and laparoscopic surgical procedures where instruments are inserted into the body through a cannula. The ReNew XR Handpiece with Reference Markings is pressure tested to ensure that insufflation can be retained during laparoscopic surgery. The ReNew XR Handpiece with Reference Markings does not produce energy but can be connected to any commercially available and legally marketed standard monopolar electrosurgical generator. In combination with such

a generator, the ReNew XR Handpiece with Reference Markings delivers monopolar electrocautery (electrical) energy to the patient, in which the current is applied through a handheld active electrode and travels back to the electrosurgical generator through a return electrode attached to the patient, so that the patient is part of the electrical circuit. The ReNew XR Handpiece with Reference Markings can be used with a legally marketed third party electro-surgical high frequency generator which complies with IEC 60601-1-1 safety and IEC 60601-1-2 electromagnetic compatibility requirements. After use in a procedure, the subject device can be reprocessed via a validated cleaning and steam sterilization procedure as described in the Instructions for Use.

Like the predicate device, the subject devices are made of six primary components including the Handle Assembly, Turning Knob, Top Cover, Cautery and Flushing Port Assembly, Inner Rod and Outer Tube Assembly.

Variations of the subject devices include varying handle length and presence or absence of a ratcheting mechanism. Details of the composition of each model number are shown in the table below.

The predicate device, ReNew XR Handpiece [510(k): K201884] 510(k), and the subject device both require end effectors for use. The end effectors are not the subject of the current 510(k) and continue to be legally marketed under the existing FDA clearance. Performance testing of the handpiece includes use of appropriate end effectors.

There are no medicinal substances associated with the subject devices. There is no use of animal tissue in manufacturing of the subject devices, and they are not made with Natural Rubber Latex, BisphenolA, Vinyl (PVC) or Phthalates.

The subject devices are supplied as non-sterile and intended to be cleaned and sterilized by a medical facility before use.

Table: Description of Product Variants

Model Number	Description
3943M	25cm length, non-ratcheted, one-piece
3941M	34cm length, non-ratcheted, one-piece
3942M	42cm length, non-ratcheted, one-piece
3946M	25cm length, ratcheted, one-piece
3944M	34cm length, ratcheted, one-piece
3945M	42cm length, ratcheted, one-piece

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The ReNew XR Handpieces and tips are indicated for cutting, grasping, dissecting, and coagulation of tissue in endoscopic and laparoscopic procedures.

The ReNew XR Handpiece is also indicated for reference length measurement of tissue during endoscopic and laparoscopic surgical procedures.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The ReNew XR Handpiece with Reference Markings and the ReNew XR Handpiece have the same intended use as both devices are to be used during laparoscopic surgeries, however, the indications have changed to add a reference measurement to the ReNew XR with Reference Markings. These measurements help to facilitate laparoscopic surgeries, where a rough estimate of tissue size is helpful in facilitating the procedure.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The technological characteristics, principle of operation, design, and material of the ReNew XR Handpiece with Reference Markings and the ReNew XR Handpiece are nearly identical. Both devices are made of six primary components including the Handle Assembly, Turning Knob, Top Cover, Cautery and Flushing Port Assembly, Inner Rod, and Outer Tube Assembly. The main difference is the ReNew XR Handpiece with Reference Markings has the addition of lines and markings printed on the handpiece shaft to be used for reference length measurements. The ink that is used for these lines is the same ink that is currently used on the ReNew XR Handpiece device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Cleaning and sterilization testing for the reusable ReNew XR Handpiece was conducted per ANSI/AAMI/ISO 17665-1: 2006, Sterilization of health care products – Moist heat Requirements for the development, validation and routine control of sterilization process for medical devices and AAMI TIR30:2011. Detailed instructions and parameters for cleaning and sterilization are provided in the instructions for use. Complete details on the cleaning and sterilization testing, as well as associated shelf life and use life testing, are provided in the Reprocessing, Sterility, and Shelf-Life section (PD102-171R, PD102-172R, and PD102-244R).

Biocompatibility testing was performed per ISO 10993-1:2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process. The devices were considered blood contact and blood/body fluid/tissue contact devices. Complete

details on biocompatibility testing are provided in the Biocompatibility section (PD102-243R).

Electromagnetic compatibility and electrical safety testing was conducted per ISO 60601 Medical Electrical Equipment, using a legally marketed electrosurgical generator as an energy source. Complete details on electrical safety and electromagnetic compatibility testing are provided in the EMC, Wireless, Electrical, Mechanical, and Thermal Safety section (PD60-168R)

Bench performance testing of the device included mechanical strength testing, flushing flow testing for cleaning, trocar compatibility, insufflation testing, impact resistance testing, and ex vivo testing of thermal spread during electrocoagulation. Complete details on bench performance testing are provided in the Performance section; Bench Tests (PD102-179R, PD102-186R, PD60-168R, PD102-096R, PD102-097R, PD60-160R, PD102-167R, and PD102-168R)

There is no clinical (human) performance data concluded, existing, or acquired for the ReNew XR Handpieces with Reference Markings to evaluate its clinical performance.

Based on the minimal design changes and the testing performed (PD102-239R; Animal Lab Report), the subject device is as safe as the predicate device, as effective at cutting, dissecting, grasping, and effective at reference measurement.