October 21, 2020

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

Re: K201884
Trade/Device Name: ReNew XR Handpiece, ReNew XR Handpiece 34cm, ReNew XR Handpiece 42cm, ReNew XR Handpiece 25cm, Ratcheted ReNew XR Handpiece 34cm
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 18, 2020
Received: September 21, 2020

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 (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)*
K201884

Device Name
ReNew XR Handpiece

Indications for Use *(Describe)*
The ReNew XR Handpiece is indicated for cutting, grasping, dissecting, and coagulating tissue during endoscopic (inclusive of 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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5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

Company:	Scott Marchand Davis Director, RA/QA Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA Telephone: 978-922-9810 Fax: 978-922-9209 smarchanddavis@microlinesurgical.com
Contact:	Scott Marchand Davis Director, RA/QA Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA Telephone: 978-922-9810 Fax: 978-922-9209 smarchanddavis@microlinesurgical.com
Date Summary Prepared:	July 6, 2020

5.2 Name of the Device

Trade Name:	ReNew XR Handpiece
Common Name:	Manual Detachable Surgical Instruments
Classification Name:	General & Plastic Surgery
Review Panel:	General & Plastic Surgery (SU)
Regulation:	878.4400
Class:	Class II
Product Code:	GEI

5.3 Substantial Equivalence Claimed to Predicate Device

The ReNew XR Handpiece is substantially equivalent to the RE-NEW LAPAROSCOPIC INSTRUMENTS (K962119), manufactured by MICROLINE PENTAX, INC.

5.4 DEVICE DESCRIPTION

The ReNew XR Handpiece 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), to cut, grasp, and dissect various tissues for use in endoscopic, including laparoscopic, surgical procedures where instruments are inserted into the body through a cannula. The ReNew XR Handpiece is pressure tested to ensure that insufflation can be retained during laparoscopic surgery. The ReNew XR Handpiece 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 delivers monopolar electrocautery (electrical) energy to the patient, in which the current is applied through a hand-held 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 can be used with a legally-marketed third party electrosurgical 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.

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, presence or absence of a ratcheting mechanism, and single-piece vs. modular (three piece) instruments. Details of the composition of each model number are shown in Table 5.1 below.

The predicate device ReNew Laparoscopic Handpiece [510(k): K962119] 510(k) submission also included end effectors used with the handpiece. These 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 (see Section 18 (Performance Testing - Bench) and Section 19 (Performance Testing - Animal)) 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, Bisphenol-A, Vinyl (PVC) or Phthalates.

The subject devices are supplied as non-sterile and intended for cleaning and sterilization by a medical facility before use.

Table 5.1: Description of Product Variants

Model Number	Description
3941	34cm length, non-ratcheted, one-piece
3942	42cm length, non-ratcheted, one-piece
3943	25cm length, non-ratcheted, one-piece
3944	34cm length, ratcheted, one-piece
3945	42cm length, ratcheted, one-piece
3946	25cm length, ratcheted, one-piece
3530	34cm length, non-ratcheted, modular three-piece

3531	42cm length, non-ratcheted, modular three-piece
3532	34cm length, ratcheted, modular three-piece
3533	42cm length, ratcheted, modular three-piece

5.5 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Like the predicate device, the subject device is composed of six primary components including the Handle Assembly, Turning Knob, Top Cover, Cautery and Flushing Port Assembly, Inner Rod and Outer Tube Assembly. The subject device is virtually identical to the predicate in terms of indication for use and operation, and is substantially equivalent in design, technological characteristics, materials, and labeling .

The most significant differences between the predicate device and the subject are the following:

1. The seal between the handpiece tip and the accessory tips has been changed from an elastomer o-ring to a solid overmolded polyvinylidene fluoride bushing to improve service life.

2. The internal metal components of the overmolded variable and fixed handles have been changed to improve insulation to the ratchet and hand grip areas during electrosurgery.

3. The color of the top cover and rotation knob has been changed from black to grey.

Both the subject devices and predicate devices are supplied as non-sterile and intended for cleaning and sterilization by a medical facility before use.

5.6 INDICATIONS FOR USE

The ReNew XR Handpiece is indicated for cutting, grasping, dissecting, and coagulating tissue during endoscopic (inclusive of laparoscopic) surgical procedures. Contraindications: None known.

5.7 PERFORMANCE DATA

The subject device’s performance characteristic testing requirements were assessed in accordance to the requirements set forth in 21 CFR § 820 for Quality System Regulation (QSR), under the FD&C Act, including current Good Manufacturing Practices (cGMP) requirements under this regulation and Microline Surgical, Inc. (hereafter referred to as MSI or Microline) internal procedures documented and applicable within the Corporate Quality System and Product Development procedures.

Bench performance testing was performed as design verification testing and to establish Substantial Equivalence to the predicate device. The functional testing for the subject devices primarily included non-clinical (ex vivo and animal) testing, electrical safety testing, cleaning and sterilization validation, and biocompatibility testing. The testing establishes that subject device is Substantially Equivalent to the predicate device in fundamental technology, design, or performance. There were no new risks or safety, or effectiveness issues raised in the testing results. The subject devices are supplied as non-sterile and intended for cleaning and sterilization by a medical facility before use.

Biocompatibility Testing:

Pursuant to ISO 10993-1:2009/AC: 2010 - Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process; 21 § CFR Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies; and FDA's Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", [issued on: June 16, 2016], which includes the FDA-modified matrix designating the type of testing for biological evaluation, the biological assessment of the subject devices was conducted.

The biological evaluation testing matrix specific considerations for the following testing:

o Cytotoxicity as recommended per ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;

o Intracutaneous Reactivity, as recommended per ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;

o Delayed type Sensitivity, as recommended per ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;

o Acute Systemic Toxicity testing, as recommended per ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity; and

o Pyrogenicity, as recommended per ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity, to address the risks evaluation associated with the presence of bacterial endotoxins.

o Sample Preparation, as outlined in the ISO 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials, was employed for the sample preparation using surface area to extract volume ratios.

For the subject devices, biocompatibility testing successfully established that the subject devices did not raise any new risks, and that they were determined to be biologically safe.

5.8 SUBSTANTIAL EQUIVALENCE CONCLUSION

Based upon the similarities in materials of construction, device design, performance, fundamental technology and the intended use/indications for use, including assessments of the impact of the proposed modifications to the subject devices, the subject devices are deemed Substantially Equivalent to their legally marketed predicate device, ReNew Laparoscopic Handpiece [510(k): K962119]. Liketheir predicate device, the subject devices are Class II devices per 21 CFR § 878.4400, Subpart E, Product Code GEI, which under this classification category is identified as Electrosurgical Cutting and Coagulation devices and accessories.

SUBSTANTIAL EQUIVALANCE STATEMENT:

The subject devices do not raise new questions of safety and effectiveness, and have been demonstrated to be at least as safe and effective as their legally marketed predicate device ReNew Laparoscopic Handpiece [510(k): K962119].