March 2, 2022

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

Re: K213127
Trade/Device Name: ReNew Disposable Scissor Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 10, 2022
Received: January 26, 2022

Dear Scott 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, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213127

Device Name
ReNew Laparoscopic Instruments Disposable Scissor Tips

Indications for Use *(Describe)*
Indications for Use:

The ReNew single patient use disposable scissor tips are to be used with the ReNew Laparoscopic Hand Pieces and they are indicated for cutting and coagulation of tissue in 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary

[As Required by 21 CFR § 807.92]

I. SUBMITTER:

Applicant:	Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA
Establishment Registration Number:	1223422
Contact Representative:	Mr. Scott Marchand Davis Director, QA/RA Microline Surgical, Inc. Phone: 978-867-1758/Fax: 978-922-9209 Email: smarchanddavis@microlinesurgical.com
Date Prepared:	February 22, 2022

II. DEVICE:

Device Trade or Proprietary Name:	ReNew Laparoscopic Instruments Disposable Scissor Tips
Common Name:	Manual Detachable Surgical Instruments
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation:	21 CFR § 878.4400
Classification:	Class II
Regulation Medical Specialty:	GEI
510(k) Review Panel:	General and Plastic Surgery.
Accessories for Subject Device:	None. [This submission is for the Disposable Scissor Tips; the ReNew Handpiece, to which it attaches, is the subject of a separate 510(k) clearance]

III. PREDICATE DEVICE:

Predicate Device:

"Re-New" Laparoscopic Instruments [510(k): K962119]

IV. DEVICE DESCRIPTION:

This Traditional 510(k) Submission is being submitted for an update to the ReNew Disposable Scissor Tips. The current ReNew Disposable Scissor Hub Assembly is being updated in an effort to decrease assembly labor. The threaded joint between the front hub and backhub is being replaced by overmolding the backhub directly onto the front hub. Due to this change an additional change needed to be made to the heat shrink on the scissor tip. An adhesive is needed to seal the heat shrink to the backhub to prevent moisture passing through and to prevent an electrical pathway.

This submission is also intended to "catch up" incremental modifications to the predicate device [510(k): K962119] that were incorporated over time.

The subject devices are made of ten (10) primary components which includes the following:

- Front Hub
- Overmolded Back Hub
- Disc Spring
- Yoke
- Yoke Pin
- Crimp Pin
- Short Blade
- Long Blade
- Surgislip Lubricant
- Heat Shrink with Adhesive Polymer

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 sterile. In accordance to 21 CFR § 801.109, Subpart D, the labeling for the devices will indicate for prescription (Rx) use only.

V. INDICATIONS FOR USE:

Device Name:

ReNew Laparoscopic Instruments Disposable Scissor Tips

Indications for Use:

The ReNew single patient use disposable scissor tips are to be used with the ReNew Laparoscopic Hand Pieces and they are indicated for cutting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.

Contraindications:

The ReNew single patient use disposable scissor tips are not intended for use except as indicated.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Overall, the subject devices, in comparison to their predicate device, are similar in the fundamental technology, intended use, and materials used in the method of construction. The primary differences between the predicate device and the subject include the following:

1. Change from two-piece hub assembly to one-piece overmolded hub
2. Minor change to heat-shrink tubing to include an adhesive layer

To provide further detail, the current ReNew Disposable Scissor Hub Assembly requires that hub assemblies be created by screwing the front hub to the back hub and adding epoxy before they can be used on the automated assembly line. The threaded joint between the front hub and backhub is being replaced by overmolding the backhub directly onto the front hub, which is done by an outside vendor. This eliminates the labor required of Microline employees to create the hub assembly. The new overmolded hub assembly does not have a threaded joint or epoxy. The updated front hub has a crisscross pattern that the back hub is overmolded on to. The predicate device back hub is made from PEEK and the subject device back hub is made from Radel. All appropriate testing has been performed on the Radel back hubs to ensure they meet requirements.

Due to the change to the hub design, an additional change needed to be made to the heat shrink on the scissor tip. The current heat shrink, MT5000, is made from polyolefin tubing. The updated heat shrink, MT5000A, is the same base material and has an inner polymer lining made of ELVAX 760, an ethylene vinyl acetate copolymer. The polymer layer acts as an adhesive for heat shrink. It melts as the polyolefin tubing shrinks, providing a seal to insulate and prevent passage of moisture.

The following table shows a comparison of the subject and predicate devices:

Characteristics	Predicate Device [510(k): K962119]	Subject Device [510(k): K213127]
Trade or Proprietary Name	"Re-New" Laparoscopic Instruments	ReNew Laparoscopic Instruments Disposable Scissor Tips
510(k) Number	K962119	K213127
510(k) Clearance Date	August 9th, 1996	Not Applicable
Classification	Class II 21 CFR § 878.4400	Class II 21 CFR § 878.4400
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories
Classification Product Code	GEI	GEI

Common Name	Manual Detachable Surgical Instruments	Manual Detachable Surgical Instruments
Marketed Brand Name	ReNew Disposable Scissor Tips	ReNew Disposable Scissor Tips
Regulation Medical Specialty	General and Plastic Surgery	General and Plastic Surgery
Environment of Use	Hospital, Operating Room (OR)	Hospital, Operating Room (OR)
Intended Use	**Indications for Use Statement:** Endoscopic (inclusive of laparoscopic) Surgical Procedures **Contraindications:** None listed	**Indications for Use Statement:** The ReNew single patient use disposable scissor tips are to be used with the ReNew Laparoscopic Hand Pieces and they are indicated for cutting and coagulation of tissue in endoscopic and laparoscopic surgical procedures. **Contraindications:** The ReNew single patient use disposable scissor tips are not intended for use except as indicated. *(The proposed changes reflect additional clarification regarding use with ReNew Laparoscopic Instrument Handpieces based on classification regulations and understood coagulation usage when connected to a legally marketed Electrosurgical unit/Radiofrequency generator. Test data further supports such usage)*
Target Population *(Major Surgical Discipline)*	All Major Surgical disciplines. Primarily Laparoscopic/General Surgery.	All Major Surgical disciplines. Primarily Laparoscopic/General Surgery.
Technological Characteristics Comparison *(Similarities and Differences)*		
Category	**Predicate Scissors**	**Modified Scissors**
Device Functionality	The ReNew single use disposable scissor tips are to be used with the ReNew Laparoscopic Hand Pieces and they are indicated for cutting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.	Identical

Principle of Operation	Cutting of tissue is a manual process achieved by using the ReNew Disposable Scissor Tip with a compatible ReNew Laparoscopic Handpiece. Coagulation is achieved by connecting the handpiece to a legally marketed monopolar electrosurgical generator (ESG).	Identical
Energy Source	Electrosurgical Generator	Identical
Energy Used and/or delivered	High frequency monopolar	Identical
Method of Actuation	The scissor tips are actuated by the ReNew handpiece	Identical
IEC Compliance Testing	IEC 60601-1: 2005	IEC 60601-1 (3rd edition) IEC60601-1-2 (4th edition) IEC60601-2-2 (6th edition)
Mechanical Safety	Meets IEC 60601-1 safety requirements	Identical
Chemical Safety	Meets IEC 60601-1 safety requirements	Identical
Electrical Safety	Meets IEC 60601-1 safety requirements	IEC 60601-1 (3rd edition) IEC60601-1-2 (4th edition) IEC60601-2-2 (6th edition)
Thermal Safety	Meets IEC 60601-1 safety requirements	Identical
Radiation Safety	Meets IEC 60601-1 safety requirements	Identical
Device Environmental Compatibility	Meets IEC 60601-1 safety requirements	Identical
Human Factors Engineering/ Usability Testing	Meets IEC 60601-1 safety requirements	Meets IEC 60601-1 safety requirements including ISO 62366
Biological Evaluation Testing	Meets ISO 10993-1 requirements.	10993-1: 2018 10993-5: 2009 10993-10: 2010 10993-11: 2017 10993-12: 2012
Device Components	• Front Hub • Back Hub (PEEK) • Epoxy • Disc Spring • Yoke • Yoke Pin • Crimp Pin • Short Blade	• Front Hub • Overmolded Back Hub (Radel) • Disc Spring • Yoke • Yoke Pin • Crimp Pin • Short Blade

	• Long Blade • Surgislip Lubricant • Heat Shrink (MT5000)	• Long Blade • Surgislip Lubricant • Heat Shrink with Adhesive Polymer (MT5000A)
Dimensional Specifications *(Endoccut Scissor)*	Blade Length: 0.733 in Thread Length: 0.489 in Heat Shrink - max diameter after shrinking: 0.208 in Hub Diameter: 0.203 in	Identical
Length *(Assembly)*	2.327 Inches	Identical
Assembly	Epoxy used to attach front hub and backhub.	Backhub overmolded on front hub. Adhesive layer used on heat shrink tubing.
Materials *(Patient Contact and Non-Patient Contact)*	The device primary components materials comparison and blood contact information is included in the **Section 12** for **Substantial Equivalence** in this submission.	The device primary components materials comparison and blood contact information is included in the **Section 12** for **Substantial Equivalence** in this submission.
Sterilization Method	Ethylene Oxide	Identical
Intended for Reuse	No	Identical
Sterile Barrier	Tyvek / LDPE Pouch	Tyvek/Nylon Pouch
Packaging	Solid Bleached Sulphate Box	Identical
Patient Contact	Yes	Yes
Blood/Fluid Contact	Yes **Primary Blood/Fluid Component:** Blades	Yes **Primary Blood/Fluid Component:** Blades
Shelf-Life/Usability	Single-Use	Identical
Special Conditions *(Shipping and Handling)*	No	No
Subject Device Manufacturing and Distribution		
Business Type:	**Address:**	**Address**
Legal Manufacturer	**Located at:** Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA **Registration Number:** 1223422	**Located at:** Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA **Registration Number:** 1223422
Market Distribution	**Manufacturer:**	**Manufacturer:**

(Brand Labeling and Market Distribution)	Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA **Registration Number:** 1223422	Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA **Registration Number:** 1223422

In comparison to their predicate device, the subject devices are identical in fundamental technology and intended use. The subject devices are supplied as sterile.

VII. PERFORMANCE DATA:

The subject device's performance characteristic testing requirements were assessed in accordance with 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) internal procedures documented and applicable within the Corporate Quality System and Product Development procedures.

Bench performance testing was performed on the subject devices to establish that the subject devices meet the performance specifications criteria to determine Substantial Equivalence with their legally marketed predicate device. In accordance with design controls, the design verification testing was performed for the subject devices. The functional testing for the subject devices primarily included:

- Cutting equivalency to the currently marketed device
- Assembly and disassembly to the ReNew Handpiece
- Heat-shrink printing adhesion
- Tissue thermal spread
- Ethylene Oxide (EO) Sterilization Validation
- Electrical Safety and EMC testing per IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2

Fundamentally, the subject device is Substantially Equivalent in fundamental technology and identical in intended use to its legally marketed predicate device. There were no new risks or safety, or effectiveness issues raised in the bench testing results. The subject devices are supplied as sterile.

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 included the following testing:

- **Cytotoxicity** (ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for* in vitro *cytotoxicity*);
- **Intracutaneous Reactivity**, as recommended per, ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*);

- **Delayed type Sensitivity**, as recommended per, ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*); and
- **Acute Systemic Toxicity** testing, as recommended per ISO 10993-11, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity).*
- **Pyrogenicity**, as recommended per ISO 10993-11, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity),* to address the risks associated with the presence of chemical pyrogens in the material.

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.

Performance Testing – Animal:

Animal testing was performed to test the coagulation performance of the ReNew disposable tips with overmolded Radel backhubs and redesigned ReNew handpieces. The study was conducted in compliance with the Food and Drug Administration Good Laboratory Practice Regulations.

The nonclinical (animal) testing demonstrated that the subject devices met all the design and pre-determined performance specifications to demonstrate their intended use.

VIII. SUBSTANTIAL EQUIVALANCE CONCLUSION:

Based upon the similarities in materials of construction, device design, performance, fundamental technology and the intended use, including the modifications to the design applicable to the subject devices, MSI has determined that the subject devices are deemed Substantially Equivalent to their legally marketed predicate device, "Re-New" Laparoscopic Instruments [510(k): K962119]. Similar to their predicate device, the subject devices are Class II devices per 21 CFR § 878.4400, Product Code GEI, which under this classification category is identified as Electrosurgical, Cutting & Coagulation & Accessories. The predicate 510(k), K962119, was originally submitted for both the disposable scissor tips and the ReNew Handpiece. This new submission is solely for the disposable scissor tips. The ReNew Handpiece has been updated and cleared recently in submission K201884.

SUBSTANTIAL EQUIVALANCE STATEMENT:

The subject device does not raise new questions of safety and effectiveness and testing and evaluation demonstrates that it is at least as safe and effective as the legally marketed predicate, "Re-New" Laparoscopic Instruments [510(k): K962119].