DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 19, 2016

Microline Surgical Incorporated
Anu Gaur, Ph.D., MBA, MSRA, RAC
Regulatory Affairs Manager
50 Dunham Road, Suite 1500
Beverly, Massachusetts 01915

Re: K160706
Trade/Device Name: ReNew V Handpiece Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 19, 2016
Received: August 22, 2016

Dear Dr. Gaur:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160706

Device Name
ReNew V Handpiece Laparoscopic Instruments

Indications for Use *(Describe)*
Cutting and Dissecting Various Abdominal 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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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:	Anu Gaur, Ph.D., MBA, MSRA, RAC Regulatory Affairs Manager Microline Surgical, Inc. Phone: 978-867-1726 Fax: 978-922-9209 Email: agaur@microlinesurgical.com
Date Prepared:	October 17, 2016

II. DEVICE:

Device Trade or Proprietary Name:	ReNew V Handpiece Laparoscopic Instruments
Common Name:	Manual Detachable Surgical Instruments
Classification Name:	Electrosurgical Cutting and Coagulation device and 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:	Cautery Post & Ring Inserts

III. PREDICATE DEVICE:

Predicate Device:	ReNew Laparoscopic Instruments, K962119

IV. DEVICE DESCRIPTION:

The subject device ReNew V Handpiece Laparoscopic Instruments is a modification to its legally marketed predicate device ReNew Laparoscopic Instruments (K962119). The predicate device ReNew Laparoscopic Instruments (K962119) included the Reusable Hand Piece and the Disposable and Reusable Scissor Tips. The incremental modifications declared in this Traditional 510(k) Submission apply to the subject device ReNew V Handpiece Laparoscopic Instruments which is a Reusable Handpiece (Handle/Shaft) Assembly only. There are no changes to the predicate Disposable and Reusable Scissor Tips (K962119).

The subject device ReNew V Handpiece Laparoscopic Instruments feature a 5mm diameter shaft for use when introduced with 5, 10/11, and 12mm instrument ports of a laparoscope or a cannula. The subject device is made of five (5) primary components, which include: Handle, Contact Pin Assembly, Turning Knob, Shaft Assembly and Flushing Port. The subject device includes variable configurations of 25cm, 34cm, and 42cm lengths; and it will be available in two optional configurations as a non-ratcheted or ratcheted Handpiece.

The subject device ReNew V Handpiece Laparoscopic Instruments can be used to deliver Monopolar High-Frequency (HF) electrical current through the active electrode contacting the patient for cutting or coagulation, dispersing energy through the patient to an inactive patient return electrode and back to the High-Frequency (HF) Generator. The subject device can be used with a U.S. FDA cleared Electrosurgical High-Frequency (HF) Generator which complies with the IEC 60601-1-2 EMC (Electromagnetic Compatibility) testing requirements. The subject device will be marketed with two (2) accessories, which include; Ring Inserts, and Cautery Post. In accordance to 21 CFR § 801.109, Subpart D, the subject device labeling is intended for Prescription use (Rx) only.

V. INDICATIONS FOR USE:

Cutting and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparoscopic) Surgical Procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of both the subject device Microline Surgical ReNew V Handpiece Laparoscopic Instruments and the predicate device ReNew Laparoscopic Instruments (K962119), are identical in terms of the Fundamental Technology and the Intended use. The modifications to the subject device ReNew V Handpiece Laparoscopic Instruments as compared to its legally marketed predicate device ReNew Laparoscopic instruments (K962119), include a material change with an over-molded Extended Retention Seal (XRS) which is an O-Ring; and minor changes to the Handpiece Assembly Shaft design.

VII. PERFORMANCE DATA:

Microline Surgical ReNew V Handpiece Laparoscopic Instruments performance characteristics 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., internal procedures documented and applicable within the Corporate Quality System and Product Development procedures.

The bench performance testing was performed based upon the subject device Renew V Handpiece Laparoscopic Instruments performance specifications criterion to determine the substantial equivalence with its legally marketed predicate device. A full design verification testing was performed including the following: axial pull, impact, thread shear, ball pull, autoclave, electrical handle, electrical safety, insulation tube adhesion, flushing flow, insufflation, stiffness, trocar, tip torque, ratchet strength, biocompatibility, sterilization and cleaning (automated and manual), distribution and packaging testing. Fundamentally, the subject device ReNew V Handpiece Laparoscopic Instruments is substantially equivalent in Fundamental Technology and identical in Intended use to its legally marketed predicate device ReNew Laparoscopic Instruments (K962119). There were no safety or effectiveness issues raised in the bench testing results.

Biocompatibility Testing:

Pursuant to the ISO 10993-1:2009/AC: 2010 - Biological Evaluation of Medical Devices - Part 1: *Evaluation and testing within a risk management process*; and 21 § CFR Part 58 - *Good Laboratory Practice for Nonclinical Laboratory Studies*; were performed for the subject device ReNew V Handpiece Laparoscopic Instruments. The distal shaft and tube end is the blood/patient contact portion of the subject device ReNew V Handpiece Laparoscopic Instruments, which was considered for the biocompatibility testing.

The following tests were performed for the biocompatibility assessment of the subject device.

1. Cytotoxicity
2. Kligman Maximization Test
3. Intracutaneous Injection Test
4. Acute Systemic Injection
5. Rabbit Pyrogen Test (Material Mediated)

There were no safety or effectiveness issues raised in the biocompatibility testing results.

Performance Testing (Animal) Laboratory Data:

There was no acute laboratory (animal) testing data concluded for the subject device ReNew V Handpiece Laparoscopic Instruments for its design evaluation. There is no change to the fundamental technology and intended use of the subject device ReNew V Handpiece Laparoscopic Instruments as compared to its predicate device ReNew Laparoscopic Instruments (K962119).

Performance Testing (Clinical) Data:

There is no clinical (human) performance testing data concluded, existing or acquired for the subject device ReNew V Handpiece Laparoscopic Instruments to evaluate the clinical performance.

VIII. SUBSTANTIAL EQUIVALANCE CONCLUSION:

Conclusively, based upon the similarities in materials of construction, device design, fundamental technology and the intended use, the modifications applicable to the subject device ReNew V Handpiece Laparoscopic Instruments, it is deemed Substantially Equivalent (SE) to its legally marketed predicate device ReNew Laparoscopic Instruments (K962119).