DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 22, 2017

Getsch + Hiller Medizintechnik GmbH
Werner Hiller
CEO
Sattlerstraße 20
Tuttlingen, 78532 Germany

Re: K171523
Trade/Device Name: Monopolar Single Use Laparoscopic Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 22, 2017
Received: May 25, 2017

Dear Werner Hiller:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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

Enclosure

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)*

K171523

Device Name

Monopolar Single Use Laparoscopic Instruments

Indications for Use *(Describe)*

Cutting, Grasping and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparosopic) Surigcal 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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DATE OF APPLICATION: 22.05.2017

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1. Device Name

Trade Name:	Monopolar Single Use Laparoscopic Instruments
Common Name:	Manual Detachable Surgical Instruments
Device Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories

2. Classification / Product Code

Monopolar Single Use Laparoscopic Instruments can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical cutting and coagulation device and accessories	General & Plastic Surgery	General & Plastic Surgery	GEI	878.4400	2

3. Predicate Device / Reference Device

Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
Monopolar Single Use Laparoscopic Instruments	ReNew V Handpiece Laparoscopic Instruments	-	K160706	Microline Surgical Inc.
	-	Disposable Re-New Forceps	K974066	Microline Pentax, Inc.

4. Device Description

The Monopolar Single Use Laparoscopic Instruments of Getsch + Hiller is available in two different designs. It is available as system consisting of two parts and as a system consisting of four parts.

The 2-part system is available with reusable handle assembled with a completely insulated shaft on which only a single use tip has to be fixed by the user. This has a working length of 330 mm.

The 4-part system consists of a reusable handle and a reusable shaft insulated, a connection rod with easy snap lock and a single use tip. The system has to be assembled by the user. The 4-part system is available with a working length of 330 mm and 450 mm.

Different types of single use tips are offered for both systems, Maryland grasping forceps, Endoclinch grasping forceps, Aggressive grasping forceps and Johan grasping forceps. Furthermore Metzenbaum scissors in different sizes, straight or curved, are available.

The systems are intended to be used in laparoscopy. Laparoscopy is an optical examination and diagnostic procedure in which the abdominal cavity and the organs contained therein (liver, gall bladder, spleen, uterus, etc.) are mirrored with an endoscope. During a

laparoscopy, in addition to the diagnosis, surgical procedures and biopsies are also made possible whereby surgical micro-instruments are utilized. The Monopolar Single Use Laparoscopic Instruments have to be used in combination with a monopolar HF connector.

The Monopolar Single Use Laparoscopic Instruments can be connected to U.S. FDA cleared Electrosurgical HF-Generator (e.g. K02464, K053290, K94519 and other FDA cleared HF-generators) which complies with the IEC 60601-1-2 EMC (Electromagnetic Compatibility) testing requirements.

5. Indication for Use

Cutting, Grasping and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparosopic) Surgical Procedures.

6. Technological Characteristics

The technological characteristics of our Monopolar Single Use Laparoscopic Instruments are the same as the technological characteristics of the predicate device.

6.1. Device characteristics table

Company	**Getsch + Hiller Medizintechnik GmbH (New Device)**	**Microline Surgical Inc. (Predicate Device)**	**Microline Pentax, Inc. (Reference Device)**	**Result**
Device Name	Monopolar Single Use Laparoscopic Instruments	ReNew V Handpiece Laparoscopic Instruments	Disposable Re-New Forceps	-
Regulation Number	878.4400	878.4400	878.4400	Substantially Equivalent
Class	II	II	II	Substantially Equivalent
Code	GEI	GEI	GEI	Substantially Equivalent
510(k) number	-	K160706	K981389	-
Indication for Use	Cutting, Grasping and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparoscopic) Surgical Procedures	Cutting and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparoscopic) Surgical Procedures	Cutting, Grasping and Dissection Various Abdominal Tissue during Endoscopic (inclusive of laparoscopic) Surgical Procedures	Substantially Equivalent
Prescription /OTC	Prescription	Prescription	Prescription	Substantially Equivalent
Device Design	Reusable handle and disposable tip	Reusable handle and disposable tips and reusable tips	Reusable handle and disposable tips and reusable tips	Substantially Equivalent
Handle Design	Non-ratcheted	Non-ratcheted/ ratcheted	Non-ratcheted/ ratcheted	Substantially Equivalent
Tip Design	scissors or graspers	scissors tips	Graspers/ Fenestrated forceps/ "Dolphin Nose" Dissector/ "Babock"/ "Maryland" Dissector	Substantially Equivalent
Shaft Diameter [mm]	5	5	5	Substantially Equivalent

Company	Getsch + Hiller Medizintechnik GmbH (New Device)	Microline Surgical Inc. (Predicate Device)	Microline Pentax, Inc. (Reference Device)	Result
Working Length [mm]	330 / 450	250 / 340 / 420	250 / 340 / 420	Substantially Equivalent
Tip Length [mm]	10.0 – 22.5	11.2 – 19.3	18.8 -22.6	Substantially Equivalent
HF-mode	monopolar	monopolar	monopolar	Substantially Equivalent
Generators	U.S. FDA cleared Electrosurgical High-Frequency (HF) Generator which complies with the IEC 60601-1-2 EMC (Electromagnetic Compatibility) testing requirements	U.S. FDA cleared Electrosurgical High-Frequency (HF) Generator which complies with the IEC 60601-1-2 EMC (Electromagnetic Compatibility) testing requirements	-	
Rated Voltage	max. 2kVp	800 Vp – 2,65 kVp	800 Vp – 2,65 kVp	Substantial Equivalent
Single Use	Tips	Tips	Tips	Substantial Equivalent
Reusable	Handle, insulated shaft, connection rod	Tips, handle	Tips, handle	Substantial Equivalent
Delivered Condition	Reusable handle is delivered in unsterile condition. Disposable tips are delivered in sterile condition.	Reusable handle and reusable tips are delivered in non-sterile condition. Disposable tips are delivered in sterile condition.	Reusable handle and reusable tips are delivered in non-sterile condition. Disposable tips are delivered in sterile condition.	Substantial Equivalent
Sterilization Method	EO	EO	EO	Substantial Equivalent

7. Summary of technological characteristics

The proposed devices are similar in terms of design, operating principles and intended use and have similar technological characteristics as the predicate devices. The materials used on these devices are also used in the legally marketed predicate devices.

8. Performance Data

Verification and validation results demonstrate that the device performs as intended and that the Monopolar Single Use Laoaroscopic Instruments are substantially equivalent to the Predicate Device K160706.

8.1. Biocompatibility

The device has been evaluated for its biological safety according to ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process". Following endpoints have been assessed during the evaluation:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

The evaluation proofs the biological safety of the device.

8.2. Electrical Safety

To proof safety and effectiveness the device has been tested according to the requirements of EN 60601-1 and EN 60601-2-2

8.3. Sterilization and Shelf-Life

The reusable parts can be reprocessed using a validated cleaning and disinfection procedure. Steam sterilization of the reusable parts has been validated.

Disposable tips are delivered in sterile condition. EO-sterilization is used for the sterilization of the disposable tips. A sterilization validation has been conducted. Furthermore a test for Ethylene oxide sterilization residuals has been conducted. The devices passed the limits of ISO 10993-7. Sterile packaging has been tested for its peel ability of the seal, seal strength and leakage of the seal. All tests were passed by the used packaging.

9. Substantial Equivalence Summary / Conclusions

Based on available 510(k) information provided herein, our Monopolar Single Use Laparoscopic Instruments are considered to be substantially equivalent to the predicate device ReNew V Handpiece Laparoscopic Instruments and the Reference Device Disposable Re-New Forceps in terms of indication for use, materials and technology, design and performance specifications. There are no differences between the devices which would raise new issues of safety or effectiveness.