DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 30, 2015

Micro-Tech (Nanjing) Co., Ltd.
Becky Li
Manager of Quality Department
No. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K150316
Trade/Device Name: Polypectomy Snare
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: June 15, 2015
Received: June 22, 2015

Dear Becky Li,

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,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K150316

Device Name
Polyhpectomy Snare

Indications for Use *(Describe)*
The Polypectomy Snares are used endoscopically in the removal of diminutive polyps, sessile polyps, and pedunculated polyps within the GI tract.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab7

510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K150316

1. **Date of Preparation: 01/16/2015**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC
Establishment Registration Number: 3004837686
Contact Person: Becky Li
Position: Manager of Quality Department
Tel: +86-25-58646378
Fax: +86-25-58744269
Email: ln@micro-tech.com.cn

3. **Identification of Proposed Device**

Product Name: Polypectomy Snare
Common Name: Snare, Flexible
Regulatory Information
Classification Name: Endoscopic electrosurgical unit and accessories
Classification: 2
Product Code: FDI
Subsequent Product Code: FDI
Regulation Number: 876.4300
Review Panel: Gastroenterology/Urology

4. **Predicate Devices:**

GIP/MEDI-GLOBE POLYPECTOMY SNARES cleared under K943935

5. **Indications for Use**

The Polypectomy Snares are used endoscopically in the removal of diminutive polyps, sessile polyps, and pedunculated polyps from within the GI tract.

6. Device Description

The proposed device Polypectomy Snare is a sterile, single-use endoscopic device, intended to be used endoscopically in the removal diminutive polyps, sessile polyps, and pedunculated polyps from within the GI tract.

The Polypectomy Snares consists of a flexible wire cable and loop which can be extended and retracted from the snare's flexible outer sheath using a handle. When passed through an endoscope the snare can be activated to deliver a monopolar electrical current to cut and cauterize tissue with the loop. The proposed device has eighteen (18) specifications; the main differences of these specifications are dimension and if the loop can be rotatable with the rotation of the handle.

7. Identification of Predicate Device

510(k) Number: K943935

Product Name: GIP/MEDI-GLOBE POLYPECTOMY SNARES

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The test results demonstrated that the proposed device complies with the following standards:

ASTM F88/F88M-09, Standard Test Method For Seal Strength Of Flexible Barrier Materials.

ASTM F1929-12, Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration.

ASTM F1140/F1140M-13, Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages.

IEC60601-2-18:2009 Medical electrical equipment Part 2-18: Particular requirements for the safety of endoscopic equipment

ANSI/AAMI HF18:2001 Electrosurgical devices

AAMI ANSI ES60601-1:2005/(R)2012 And C1:2009/(R)2012 Medical Electrical Equipment Part 1: General requirements for safety

IEC60601-2-2:2009 Medical electrical equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment

ISO 11737-1 Second Edition 2006-04-01 Sterilization of medical devices — Microbiological methods—Part 1: Determination of a population of microorganisms on products

ASTM F1886/F1886M－09 Standard Test Method for Determining Integrity of Seals for

Flexible Packaging by Visual Inspection

ASTM F1929-12, Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration

ASTM F1980–07:2011 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

AAMI ANSI ST72:2011 bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing.

ASTM F88/F88M-09, Standard Test Method For Seal Strength Of Flexible Barrier Materials.

ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-7:2008(R) 2012, Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.

ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

USP <71> Sterility Tests.

USP 37-NF 32：2014 <85> BACTERIAL ENDOTOXINS TEST

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device	Substantial Equivalence
Product Code	FDI	FDI	Same
Regulation No.	876.4300	876.4300	Same
Class	2	2	Same
Indications for Use	The Polypectomy Snares are used endoscopically in the removal diminutive polyps, sessile polyps, and pedunculated polyps from within the GI tract.	The Polypectomy snare is intended to remove polyps and small tumors from the gastrointestinal tract with high frequency current.	Similar
Single Use	Yes	Yes	Same
Configuration	Configuration Loop, outer tube, High-Frequency, and Handle	Loop, outer tube, High-Frequency, and Handle	Same
Energy used/ Delivered	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current	Same
Loop Shape	Oval	Oval, Hexagonal, Asymmetric	Similar
Loop Diameter	Oval: 10mm, 15mm, 20mm, 24mm, 30mm, 36mm	Oval: 15mm, 20mm, 25mm, 35mm, 50mm; Hexagonal: 15mm, 25mm, 35mm; Asymmetric: 15mm, 25mm	Similar
Outer Tube Diameter	2.3mm	2.5mm	Similar
Minimal Working Channel	2.8mm	2.8mm	Same
Working Length	2300mm	1800mm, 2300mm	Similar

Electrode contact impedance	13.46±0.68	13.64±0.90	Similar
Cutting	23.75±1.14	23.42±1.62	Similar
Pushability	3.08±0.64	3.38±0.81	Similar
Performance	Electrode contact impedance, Cutting, Pushability and Tensile Strength	Electrode contact impedance, Cutting, Pushability and Tensile Strength	Same
Patient-contact Material	Stainless steel SUS304 (With Dow Corning® MDX4-4159, 50% Medical Grade Dispersion) and Polytetrafluoroethylene (PTFE)	Stainless steel SUS304 (With Dow Corning® MDX4-4159, 50% Medical Grade Dispersion) and Polytetrafluoroethylene (PTFE)	Same
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10 and USP <151>.	Comply with ISO 10993-5, ISO 10993-10, and USP <151>.	Same
Sterilization	EO Sterilized, SAL: 10^{-6}	EO Sterilized, SAL: 10-6	Same
Shelf Life	Three years	Five years	Similar
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Same

11. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis from the nonclinical tests, the proposed devices is safe and effective, perform is as well as the predicate devices. It determined to be Substantially Equivalent (SE) to the predicate devices.