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

January 21, 2016

Micro-Tech (Nanjing) Co., Ltd.
Becky Li
Manager of Quality Department
No. 10 Gaoke Third Road
National Hi-Tech, Industrial Development Zone
Nanjing 210032 Jiangsu Province
PRC

Re: K152802
Trade/Device Name: Grasping Forceps
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCZ
Dated: December 18, 2015
Received: December 21, 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)*
K152802

Device Name
Grasping Forceps

Indications for Use *(Describe)*

Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal 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: _____

1. **Date of Preparation: 11/25/2015**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, 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: Grasping Forceps
Common Name: Grasping Forceps
Regulatory Information
Classification Name: endoscopic grasping/cutting instrument, non-powered
Classification: 2
Product Code: OCZ
Regulation Number: 876.1500
Review Panel: Gastroenterology/Urology

4. **Indications for Use**

Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.

5. **Device Description**

The proposed device Grasping Forceps is a sterile, single-use device,

designed to pass through a 2.8 mm or greater working channel of an endoscope.

The main components of Grasping forceps are jaws, spring sheath and handle. Grasping forceps can be used to grasp tissue and/or retrieve foreign bodies, and excised tissue through jaws open and close.

The Grasping Forceps has six (6) specifications, the differences of these specifications are jaws open width, shape configuration of jaws and working length.

The proposed devices are EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 5 years.

6. Identification of Predicate Device

510(k) Number: K120084

Trade Name: The US Endoscopy Endoscopic Retrieval Device

Regulation Name: Endoscope and accessories

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and 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.

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 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.

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 37 NF 32: 2014 <71> Sterility Tests

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

ISO 11135 Second Edition 2014 Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device Grasping Forceps	Predicate Device (K120084) The US Endoscopy Endoscopic Retrieval Device	Substantial Equivalence
Product Code	OCZ	OCZ	Same
Regulation No.	876.1500	876.1500	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Same
Indications for Use	Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.	The US Endoscopy Endoscopic Retrieval Device is intended to be used to grasp tissue and/or retrieve foreign bodies, excised tissue and stents during endoscopic procedures.	Similar
Jaws open wide (mm)	6.3mm, 8.1mm	10mm	Similar
Working Length	1800mm, 2300mm	2300mm	Similar
Configuration	Jaws, Spring sheath, Finger ring	Jaws, Spring sheath, Finger ring	Same
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same

K152802

Item	Proposed Device Grasping Forceps	Predicate Device (K120084) The US Endoscopy Endoscopic Retrieval Device	Substantial Equivalence
Shelf Life	Five years	Three years	Similar

10. Substantially Equivalent (SE) Conclusion

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