DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 14, 2016

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

Re: K160625
Trade/Device Name: Disposable Hot Biopsy Forceps
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KGE
Dated: May 13, 2016
Received: May 17, 2016

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,

Benjamin R. Fisher -S

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)*

K160625

Device Name
Disposable Hot Biopsy Forceps

Indications for Use *(Describe)*
This device is used for endoscopic histological sampling or electrocoagulation of various tissues, within the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.

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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Tab 7

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:01/08/2016

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: Quality Director
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Fax: +86-25-58744269
Email: ln@micro-tech.com.cn

3. Identification of Proposed Device

Trade Name: Disposable Hot Biopsy Forceps
Common Name: Disposable Hot Biopsy Forceps
Classification Name: Forceps, Biopsy, Electric
Classification: 2
Product Code: KGE
Regulation Number: 876.4300
Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K953355
Trade Name: *GIP/Medi-Globe Hot Biopsy Forceps*
Common Name: Forceps, Biopsy, Electric

5. Indications for Use

This device is used for endoscopic histological sampling or electrocoagulation of various tissues, within the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.

6. Device Description

The proposed device Disposable Hot Biopsy Forceps is a sterile, single-use endoscopic device, intended to be used for endoscopic histological sampling or electrocoagulation of various tissues, within the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.

It 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 forceps can be activated to deliver a monopolar electrical current to cut polyp with the loop.

The main component of the proposed device is jaws, spring sheath and handle. The proposed device is used for endoscopic histological sampling or electrocoagulation of various tissues, within the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.

The proposed device has two (2) specifications, HBF55-11023180 and HBF55-11023230.

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 3 years.

7. Comparison of Technological Characteristics

The **Disposable Hot Biopsy Forceps** incorporates substantially equivalent device materials, design, catheter configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Medi-Globe predicate devices.

Comparison to predicate Devices:

Item	Proposed Device Disposable Hot Biopsy Forceps	Comparison to Predicate Devices
Product Code	KGE	Same
Regulation No.	876.4300	Same
Class	2	Same
Supplied Sterile	Yes	Same
Jaws Shape	Oval Jaws	Same
Outer Tube Diameter	2.3mm	Similar
Minimal Working Channel	2.8mm	Same
Working Length	1800mm, 2300mm	Same
Indications for Use	The device is intended to be used for endoscopic histological sampling or electrocoagulation of various tissues, within the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.	Similar
Configuration	Jaws, Spring Sheath, High-Frequency,	Same

Item	Proposed Device Disposable Hot Biopsy Forceps	Comparison to Predicate Devices
	and Handle	
Single Use	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Similar
Shelf Life	Four years	Similar

8. Performance Data

Bench testing was performed to support a determination of substantial equivalence. The Disposable Hot Biopsy Forceps performs as well as the predicate and is substantially equivalent to the predicate devices.

The following in-vitro performance tests were completed on the **Disposable Hot Biopsy Forceps**:

Dimension Testing Report	Electrode Contact Impedance Testing
Cutting Performance Testing	Pushability Testing
Tensile Strength Testing	Jaws Misalignment Testing
Package Integrity	Shelf Life Testing

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Disposable Hot Biopsy Forceps** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the *GIP/Medi-Globe Hot Biopsy Forceps.*