July 5, 2018

Micro-Tech (Nanjing) CO., Ltd.
Becky Li
Quality and Regulatory Affairs Director
NO. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K180018
Trade/Device Name: Disposable Hot Biopsy Forceps
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KGE
Dated: May 18, 2018
Received: May 21, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K180018

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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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: K180018

1. Date of Preparation: 05/08/2018

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.
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3. Identification of Proposed Device

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

4. Identification of Predicate Device

510(k) Number: K160625
Trade Name: Disposable 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 jaws which can be opened and closed by a handle. When passed through an endoscope the forceps can be activated to deliver a monopolar electrical current for histological sampling or electrocoagulation with the jaws.

The main component of the proposed device is jaws, spring sheath and handle.

The proposed device has four (4) models, HBF55-11023180 and HBF55-11023230, HBF65-11023180 and HBF65-11023230. HBF65-11023180 and HBF65-11023230 are two new models added. The differences between the two new models and the two approved models (predicate device) are the color of Handle and the jaws. The news models are White-blue Handle and Alligator Forceps; the two approved models are Grey-blue Handle and oval forceps.

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, configuration, manufacturing processes, sterilization process and intended use as those featured in.

Comparison to predicate Device:

Item	Proposed Device Disposable Hot Biopsy Forceps	Predicate Device Disposable Hot Biopsy Forceps (K160625)	Comparison to Predicate Device
Product Code	KGE	KGE	Same
Regulation No.	876.4300	876.4300	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Same
Jaws Shape	Oval Jaws Alligator Jaws	Oval Jaws	Similar
Outer Tube Diameter	2.3mm	2.3mm	Same
Minimal Working Channel	2.8mm	2.8mm	Same
Working Length	1800mm, 2300mm	1800mm, 2300mm	Same
Indications for Use	The device is intended to be used for endoscopic histological sampling or electrocoagulation of various tissues, within	The device is intended to be used for endoscopic histological sampling or electrocoagulation of various tissues, within the	Same

Item	Proposed Device Disposable Hot Biopsy Forceps	Predicate Device Disposable Hot Biopsy Forceps (K160625)	Comparison to Predicate Device
	the gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.	gastrointestinal and bronchial tracts, via the operating channel of endoscopic instruments.	
Configuration	Jaws, Spring Sheath, High-Frequency, and Handle	Jaws, Spring Sheath, High-Frequency, and Handle	Same
Single Use	Yes	Yes	Same
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	Same
Sterility	Sterility Assurance Level: 10^{-6}.	Sterility Assurance Level: 10^{-6}.	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Shelf Life	Three years	Four years	Different

Compared to the predicate device, the proposed device is different from the predicate device in the following:

1) Add two new models that the Jaws shape is Alligator;
2) Change the color of spring tube from blue to Red and add mark;
3) Change the packaging, delete the inner plate and add the Jaws protective cap and Fixed Tape.
4) Shelf life Change

8. Non-Clinical Test

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. Non clinical tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment, the non-clinical tests verify that the proposed device met all acceptance criteria 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-15 Standard Test Method For Seal Strength Of Flexible Barrier Materials.

ASTM F1929-15 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

ASTM F1886/F1886M–16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

USP 40 - NF35:2017 <71> Sterility Tests
ASTM F1980–16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 10993-1:2009 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-10: 2010 Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11: 2006 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
USP 40 NF 35:2017 <151> Pyrogen 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

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 **Disposable Hot Biopsy Forceps cleared under K160625.**