May 6, 2022

Micro-Tech (Nanjing) Co., Ltd.
Becky Li
Senior Quality and Regulatory Affairs Director
No. 10 Goake Third Road, Nanjig National Hi-Tech Industrial
Development Zone
Narijing, Jiangsu Province 210032
CHINA

Re: K211021
Trade/Device Name: Sterile Biliary Stone Retrieval Balloon Catheter, Retrieval Balloon / short-wire compatible
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: March 28, 2022
Received: April 4, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211021

Device Name
Retrieval Balloon Catheter

Indications for Use *(Describe)*
The Retrieval Balloon Catheter is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

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.

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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: **K211021**

1. **Date of Preparation: 2022-05-04**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

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3. **Identification of Proposed Device**

Trade/Product Name: Sterile Biliary Stone Retrieval Balloon Catheter, Retrieval Balloon / short-wire compatible

Common Name: Retrieval Balloon Catheter

Regulatory Information

Classification Name: Biliary Catheter and Accessories

Classification: 2

Product Code: FGE

Regulation Number: 876.5010

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(K) Number: K102082

Product Name: Extractor™ Pro Retrieval Balloon Catheter

Manufacturer: Boston Scientific Corporation

5. Indications for Use

The device is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

6. Device Description

The proposed device Retrieval Balloon Catheter includes Sterile Biliary Stone Retrieval Balloon Catheter (hereafter referred as Category 1) and Retrieval Balloon / short-wire compatible (hereafter referred as Category 2). Category 1 is commonly used in traditional ERCP surgery with a long guidewire (4.5m) while Category 2 adopts short-wire design which is compatible with a short guidewire (2.6m). For specifications of Category 2, the main feature of the short wire design is the C-shaped groove on the sidewall of catheter which is used to separate guidewire from the proposed device. The guidewire can be locked in place using Guidewire Locking Device to maintain guidewire access. Then the exchange of various devices can be performed without concern over wire displacement.

The proposed device Retrieval Balloon Catheter is sterile, single-use endoscopic device, and is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

The proposed Retrieval Balloon Catheter is comprised of a natural latex balloon mounted at the distal end of a Pebax catheter with three internal lumens for ballooning, guidewire and contrast medium. The internal lumen for ballooning is used to inflate/deflate the balloon. Multiple syringes are included with the packaging, allowing balloon inflation to a specific diameter.

Following insufflation, the balloon surface lies flat against the bile duct wall, enabling efficient and complete cleaning of the bile duct. A separate lumen is designed for a 0.035 inch guidewire and the guidewire is able to be loaded either from the front or the back. Another separate lumen is designed for contrast medium. There are for injection-distal or injection-proximal options offered to support physician preference and facilitate procedural needs.

The balloon can be inflated to 9 mm, 12 mm, 15 mm, 18 mm and 21 mm diameters using the pre-measured syringes and a single balloon can be inflated to two or three distinct sizes if a different diameter is needed without having to exchange devices. During stone removal process, the balloon can be filled to removal multiple stones in the biliary tract.

Balloon Inflated Diameter	9/12	12/15	9/12/15	15/18	12/15/18	18/21	15/18/21

There are two radiopaque bands placed at the distal and proximal ends of the balloon providing high fluoroscopic visualization of the balloon location.

7. Comparison of Technological Characteristics

The **Retrieval Balloon Catheter** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Extractor™ Pro Retrieval Balloon Catheter.

Table 7.1 Technological comparison between the proposed device and predicate device

Item	Proposed Device Retrieval Balloon Catheter	Predicate Device Extractor™ Pro Retrieval Balloon Catheter **(K102082)**	Remark
Product Code	FGE	FGE	Same
Regulation No.	876.5010	876.5010	Same
Class	II	II	Same
Supplied in Sterile	YES	YES	Same
Configuration	Catheter, Balloon, Radiopaque Marker, Handle	Catheter, Balloon, Radiopaque Marker, Handle	Same

Item	Proposed Device Retrieval Balloon Catheter	Predicate Device Extractor™ Pro Retrieval Balloon Catheter **(K102082)**	Remark
Main Material	Natural Latex, Platinum Iridium Alloy, Polyether Block Amide	Natural Latex, Polymer Materials, Alloy Materials	Similar
Injection	Contrast Medium	Contrast Medium	Same
Using Environment	Endoscopic Clinic	Endoscopic Clinic	Same
Working Length	2000 mm	2000 mm	Same
Compatible Endoscopy Working Channel	≥3.2mm	≥3.2mm	Same
Balloon Size	The Balloon Inflatable Diameter: 9mm/12mm/15mm/18mm/21mm	The Balloon Inflatable Diameter: 9mm/12mm/15mm/18mm	Similar
Indications for Use	The proposed devices are indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.	The predicate devices are indicated for use endoscopically to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.	Same
Applicable Body Parts	Biliary Tract	Biliary Tract	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
Shelf Life	12 Months	24 Months	Different
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	Same
Sterilization	EO Sterilized, SAL: 10^{-6}	EO Sterilized, SAL: 10^{-6}	Same
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Same

8. Performance Data

Performance testing was conducted to demonstrate the performance of the proposed device and confirmed that the proposed device works as intended with the compatible devices. Additionally, the results of the tests below were evaluated as substantially equivalent to the predicate device.

The bench tests below were tested and evaluated as substantially equivalent to the predicate device.

- Dimension;
- Endoscope Compatibility Test;
- Infusion Patency Testing;
- Guidewire Matching Test;
- Balloon Fatigue Test;
- Luer Connector Test;
- Connection Strength Test;

Shelf-life testing and packaging integrity testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices and ISO 11607-1:2019: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2:2019: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes. Two-years aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test.

Sterilization validation was carried out in accordance with ISO 11135:2014+A1:2018 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”.

The biocompatibility evaluation for the Retrieval Balloon Catheter was conducted in

accordance with ISO 10993-1: 2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and FDA's biocompatibility guidance, Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process (issued on September 4, 2020,) the following tests were conducted:

The biocompatibility evaluation for the was conducted in accordance with ISO 10993-1: 2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and FDA's biocompatibility guidance, Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process (issued on September 4, 2020,) the following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Pyrogen

The results of all the performance testing demonstrated that the proposed device met the acceptance criteria and support substantial equivalence to the predicate device **Extractor™ Pro Retrieval Balloon Catheter** cleared under **K102082**.

9. Animal Study

No animal study is included in this submission.

10. **Clinical Study**

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Retrieval Balloon Catheter (including Sterile Biliary Stone Retrieval Balloon Catheter and Retrieval Balloon / short-wire compatible)** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Predicate Device **Extractor™ Pro Retrieval Balloon Catheter (K102082)**.