December 16, 2024

Micro-Tech (Nanjing) Co., Ltd.
Sally He
Regional RA Manager
No.10 Gaoke Third Rd
Nanjing National Hi-Tech, Industrial Development Zone
Nanjing, Jiangsu 210032
China

Re: K243471
Trade/Device Name: Extraction Basket
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: LQR
Dated: November 8, 2024
Received: November 8, 2024

Dear Sally He:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Anthony Lee -S

Anthony Lee, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243471

Device Name

Extraction Basket

Indications for Use *(Describe)*

This device is used for the endoscopic removal of stones in the biliary system and foreign bodies.

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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510(k) 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: K243471

1. Date of Preparation: 2024-11-27

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: Sally He

Position: Regional RA Manager

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3. Identification of Proposed Device

Trade Name: Extraction Basket

Regulatory Information

Classification Name: Biliary Catheter And Accessories

Classification: 2

Product Code: LQR

Regulation Number: 21 CFR 876.5010

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K171969

Product Name:

Web II Memory Extraction Basket or Memory II Double Lumen Extraction Basket

Memory 5 Fr. Soft Wire Baskets or Memory Helical Stone Extractor

Memory Eight Wire Baskets

Fusion Wire Guided Extraction Basket

Non-Lithotripsy Extraction Basket

Manufacturer: Wilson-Cook Medical

5. Indications for Use

This device is used for the endoscopic removal of stones in the biliary system and foreign bodies.

6. Device Description

The proposed device is a sterile, single-use accessory to be used with endoscopic, intended to be used for the removal of stones in the biliary system and foreign bodies. The proposed device includes two types, one type (Hereinafter referred to Type 1) is working through the channel provided by duodenoscopy, cross the duodenal papilla and insert into the bile duct, with the assistance of Imaging field of view formed by X-ray, capture and remove stones out of bile duct. Another one (Hereinafter referred to Type 2) is working through the channel provided by choledochoscope, after the choledochoscope was inserted into the bile duct successfully, inserted the extraction basket into the bile duct by the channel of choledochoscope, capture and remove stones out of bile duct by the direct field view of choledochoscope.

The proposed device is 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 1 year for Type 1 and 3 years for Type 2.

7. Comparison of Technological Characteristics

The Extraction Basket incorporates substantially equivalent device's intended use, using environment, design, packaging fundamental technology, principles of operation, manufacturing processes including sterilization process, configuration, main material as those featured in the predicate device **Memory Eight Wire Baskets** cleared under **K171969**. Only the dimension and shelf life of proposed device are different from predicate device, which have been demonstrated not influence the safety and effectiveness of proposed device.

Item	Proposed Device Extraction Basket （Type 1）	Proposed Device Extraction Basket (Type 2)	Predicate Device **(K171969)**	Remark
Product Code	LQR	LQR	LQR	SE
Regulation No.	21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.5010	SE
Class	II	II	II	SE
Indications for Use	This device is used for the endoscopic removal of stones in the biliary system and foreign bodies.	This device is used for the endoscopic removal of stones in the biliary system and foreign bodies.	Endoscopic removal of stones in the biliary system and foreign bodies.	SE
Single Use	Yes	Yes	Yes	SE

510(k) summary

Item		Proposed Device Extraction Basket （Type 1）	Proposed Device Extraction Basket (Type 2)	Predicate Device **(K171969)**	Remark
Supplied in Sterile		Yes	Yes	Yes	SE
Configuration		Consists of Basket Assembly, Sheath, Handle assembly.	Consists of Basket Assembly, Sheath, Handle assembly.	Consists of Basket Assembly, Sheath, Handle assembly.	SE
Main Material		Metal wires	Metal wires	Metal wires	SE
Using Environment		Hospital	Hospital	Hospital	SE
Dimensions	Basket Diameter	10mm, 15 mm, 20 mm, 25 mm, 30 mm	10mm, 15 mm, 20 mm, 25 mm, 30 mm	15mm,20 mm, 25 mm, 30 mm	Similar
	Basket Length	30 mm,40 mm, 45mm,50 mm,55mm, 60 mm, 70 mm	30 mm,40 mm, 50 mm, 60 mm, 70 mm	35mm,40 mm, 50 mm,60 mm	Similar
	Outer Tube Diameter	7Fr	3Fr	5.5Fr,7Fr,8Fr,10Fr	Similar
	Compatible Endoscopy Working Channel	7Fr:≥3.7 mm	3Fr:≥1.1 mm	5.5Fr:≥2.0 mm, 7Fr:≥2.8 mm 8Fr:≥3.2 mm, 10Fr:≥4.2 mm	Similar
	Working Length	2500 mm,2000 mm	2900 mm,2000 mm,1600 mm,1200 mm,1000 mm,800 mm,600 mm	2000 mm	Similar
Principles of Operation		The device enters the human body through endoscope, advance the basket to the appropriate position, slowly open the basket, grasp the stones or foreign bodies by pull the basket over them, withdraw the catheter from the bile duct to retrieve the stones or foreign bodies	The device enters the human body through endoscope, advance the basket to the appropriate position, slowly open the basket, grasp the stones or foreign bodies by pull the basket over them, withdraw the catheter from the bile duct to retrieve the stones or foreign bodies	The device enters the human body through endoscope, advance the basket to the appropriate position, slowly open the basket, grasp the stones or foreign bodies by pull the basket over them, withdraw the catheter from the bile duct to retrieve the stones or foreign bodies	SE
Applicable Body Parts		Biliary Tract	Biliary Tract	Biliary Tract	SE
Packaging		Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	SE

8. Performance Data

The biocompatibility evaluation for Extraction Basket 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:

a) Cytotoxicity
b) Sensitization
c) Irritation
d) Acute Systemic Toxicity
e) Material Mediated Pyrogenicity

Performance testing was conducted to demonstrate the essential performance of the proposed device and confirmed that the proposed device works as intended with the compatible devices. The following tests are conducted:

Type 1 :

- Dimension Testing;
- Connection Force Testing;
- Simulated-Use Testing;
- Stone Capture and Durability Testing;
- Injection Testing;
- Luer Testing;
- X-ray Detectability Testing;

Type 2 :

- Dimension Testing;
- Connection Force Testing;
- Simulated-Use Testing;
- Stone Capture and Durability Testing.

Shelf-life testing and packaging integrity testing was conducted based on an accelerated aging test in accordance with ASTM F1980-21 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. One-year accelerated aging test was performed to demonstrate the one-year stability in the shelf life.

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".

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, safety and performance testing, **Extraction Basket** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device cleared under K171969.