September 6, 2023

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

Re: K230127
Trade/Device Name: Biliary Plastic Stent,
Biliary Plastic Stent Introducer,
Biliary Plastic Stent Set,
Biliary Plastic Stent Introducer/ short-wire compatible,
Biliary Plastic Stent Set/ short-wire compatible
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: August 2, 2023
Received: August 7, 2023

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 (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,

Glenn B. Bell -S

Glenn Bell
Division 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)*

K230127

Device Name

Biliary Plastic Stent, Biliary Plastic Stent Introducer, Biliary Plastic Stent Set, Biliary Plastic Stent Introducer/ short-wire compatible and Biliary Plastic Stent Set/ short-wire compatible

Indications for Use *(Describe)*

The Biliary Plastic Stent is used to drain obstructed biliary ducts.
The Biliary Plastic Stent Introducer is used for endoscopic biliary stent placement.
The Biliary Plastic Stent Introducer/ short-wire compatible is used for endoscopic biliary stent placement.
The Biliary Plastic Stent Set is intended for endoscopic biliary stent placement to drain obstructed bile ducts.
The Biliary Plastic Stent Set/ short-wire compatible is intended for endoscopic biliary stent placement to drain obstructed bile ducts.

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.

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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: **K230127**

1. Date of Preparation: 2023-07-28

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: RA Region Manager

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Email: ra.micro-tech@outlook.com

3. Identification of Proposed Device

Trade Device Name:	Biliary Plastic Stent Biliary Plastic Stent Introducer Biliary Plastic Stent Set Biliary Plastic Stent Introducer/ short-wire compatible Biliary Plastic Stent Set/ short-wire compatible
Product Code:	FGE
Classification Name:	Biliary Catheter And Accessories
Regulation Number:	21 CFR 876.5010
Regulatory Class:	Class II

4. Identification of Predicate Device

510(k) Number: K172044

Trade/Device Name:

Cotton-Huibregtse® Biliary Stent, Cotton-Leung® Biliary Stent, CottonLeung® Sof-Flex® Biliary Stent, ST-2 Soehendra Tannenbaum® Biliary Stent,

Zimmon® Biliary Stent, Cotton-Huibregtse® Biliary Stent Set, CottonLeung® Biliary Stent Set, Zimmon® Biliary Stent Set, Solus® Double Pigtail Stent with Introducer,

Guiding Catheter, Pushing Catheter, Fusion® Pushing Catheter, Stent Introducer Set,

Oasis® One Action Stent Introduction System,

Fusion® Oasis® One Action Stent Introduction System,

Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary Stent,

Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.

Manufacturer: Cook Ireland Ltd

5. Indications for Use

The Biliary Plastic Stent is used to drain obstructed biliary ducts.

The Biliary Plastic Stent Introducer is used for endoscopic biliary stent placement.

The Biliary Plastic Stent Introducer/ short-wire compatible is used for endoscopic biliary stent placement.

The Biliary Plastic Stent Set is intended for endoscopic biliary stent placement to drain obstructed bile ducts.

The Biliary Plastic Stent Set/ short-wire compatible is intended for endoscopic biliary stent placement to drain obstructed bile ducts.

6. Device Description

The proposed device Biliary Plastic Stent Set is a sterile, single-use endoscopic device, the device is used to drain obstructed biliary ducts. Biliary Plastic Stent Set includes Biliary Plastic Stent (hereafter referred as Category 1), Biliary Plastic Stent Introducer (hereafter referred as Category 2), Biliary Plastic Stent Set (hereafter referred as Category 3), Biliary Plastic Stent Introducer/

short-wire compatible (hereafter referred as Category 4) and Biliary Plastic Stent Set/ short-wire compatible (hereafter referred as Category 5). Category 2 and Category 3 is commonly used in traditional ERCP (short for endoscopic retrograde cholangiopancreatography) surgery with a long guidewire (4.5m) while Category 4 and Category 5 adopts short-wire design which is compatible with a short guidewire (2.6m). For specifications of Category 4 and Category 5, the main feature of the short wire design is the guide wire exit port on the inner tube or outer tube of the introducer which is used to separate guidewire from the proposed device (For Biliary Plastic Stent Introducer (Normal), the guide wire exit on the inner tube; for Biliary Plastic Stent Introducer (Pusher), the guide wire exit on the outer tube). 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.

There are 66 specifications of Category 1 which mainly differ in plastic stent shape (side bend, center bend, double pigtails), plastic stent diameter (7Fr, 8.5Fr, 10Fr, 11.5Fr) and plastic stent working length (3cm-18cm).

There are 4 specifications of Category 2 which mainly differ in introducer diameter (7Fr, 8.5Fr, 10Fr, 11.5Fr) and can be divided into two types including Biliary Plastic Stent Introducer (Normal) and Biliary Plastic Stent Introducer (Pusher) depending on whether with or without inner tube assembly.

There are 66 specifications of Category 3, each specification contains both plastic stent and introducer. The plastic stent in Category 3 is the same as that in Category 1, which mainly differ in plastic stent shape, plastic stent diameter and plastic stent working length, the introducer in Category 3 is the same as that in Category 2, which includes Biliary Plastic Stent Introducer (Normal) and Biliary Plastic Stent Introducer (Pusher). Among them, the plastic stent with a diameter of 7Fr in Category 3 corresponds to Biliary Plastic Stent Introducer (Pusher), and the rest correspond to Biliary Plastic Stent Introducer (Normal).

There are 3 specifications of Category 4 which mainly differ in introducer diameter (7Fr, 8.5Fr, 10Fr) and can be divided into two types including Biliary Plastic Stent Introducer/ short-wire compatible (Normal) and Biliary Plastic Stent Introducer/ short-wire compatible (Pusher) depending on whether with or without inner tube assembly.

There are 54 specifications of Category 5, each specification contains both plastic stent and

introducer/ short-wire compatible. The plastic stent included in Category 5 is the same as that (except 11.5Fr diameter) in Category 1, the introducer short-wire compatible in Category 5 is the same as that in Category 4, which includes Biliary Plastic Stent Introducer/ short-wire compatible (Normal) and Biliary Plastic Stent Introducer/ short-wire compatible (Pusher). Among them, the plastic stent with a diameter of 7Fr in Category 5 corresponds to Biliary Plastic Stent Introducer/ short-wire compatible (Normal), and the rest correspond to Biliary Plastic Stent Introducer/ short-wire compatible (Pusher).

The device is supplied sterile, intended for single use only, and is available for prescription use only. Use of this device is restricted to a trained healthcare professional. They have an indicated indwell of up to 3 months

7. Comparison of Technological Characteristics

The **proposed device** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device **cleared under K172044**.

Comparison to predicate Devices:

Item	Proposed Device Biliary Plastic Stent Set	Predicate Device **(K172044)**	Remark
Product Code	FGE	FGE	SE
Regulation No.	21 CFR 876.5010	21 CFR 876.5010	SE
Class	II	II	SE
Indication for Use	The Biliary Plastic Stent is used to drain obstructed biliary ducts. The Biliary Plastic Stent Introducer is used for endoscopic biliary stent placement. The Biliary Plastic Stent Introducer/ short-wire compatible is used for endoscopic biliary stent placement. The Biliary Plastic Stent Set is intended for endoscopic biliary stent placement to	The stents are used to drain obstructed biliary ducts. The introducers are used for endoscopic biliary stent placement. The systems are intended for endoscopic biliary stent placement to drain obstructed bile ducts.	SE

Item	Proposed Device Biliary Plastic Stent Set	Predicate Device **(K172044)**	Remark
	drain obstructed bile ducts. The Biliary Plastic Stent Set/ short-wire compatible is intended for endoscopic biliary stent placement to drain obstructed bile ducts.		
Single Use	YES	YES	SE
Supplied in Sterile	YES	YES	SE
Configuration	Biliary Plastic Stent only, Biliary Plastic Stent Introducer only, Biliary Plastic Stent Introducer/ short-wire compatible only, Biliary Plastic Stent Set, Biliary Plastic Stent Set/ short-wire compatible	Stents only, Introducers only/Introduction systems, Stent sets	SE
Main Material	The Biliary Plastic Stent Set is comprised of two main parts: Biliary Plastic Stent and Biliary Plastic Stent Introducer, the Biliary Plastic Stent Set/ short-wire compatible is comprised of two main parts: Biliary Plastic Stent and Biliary Plastic Stent Introducer/ short-wire compatible. The main material of plastic stent is TPU. The main material of introducer is PTFE, ABS, PC, SUS304 and Ta	The main material of plastic stent is plastic. The main material of introducer is plastic and metal.	Similar
Plastic Stent Shape	Side bend/ Center bend/ Double pigtails	Side bend/ Center bend/ Center bend with four side flaps/ Double pigtails	Similar
Plastic Stent Diameter	7Fr/8.5Fr/10Fr/11.5Fr	5Fr/7Fr/8.5Fr/10Fr/11.5Fr	Similar
Plastic Stent Working Length	30mm/50mm/70mm/90mm/100mm/ 120mm/150mm/180mm	30mm/40mm/50mm/60mm/70mm/80mm/ 90mm/100mm/110mm/ 120mm/130mm/140mm/150mm/160mm/ 170mm/180mm	Similar
Introducer Diameter	7Fr/8.5Fr/10Fr/11.5Fr	5Fr/7Fr/8.5Fr/10Fr/11.5Fr	Similar

Item	Proposed Device Biliary Plastic Stent Set	Predicate Device **(K172044)**	Remark
Introducer Working Length	1700mm/ 2200mm	1950mm/2050mm/3180mm/3200mm	Similar
Working Channel of Endoscope	7Fr: ≥2.8mm, 8.5Fr: ≥3.2mm, 10Fr: ≥3.7mm, 11.5Fr ≥4.2mm	5Fr: ≥2mm, 7Fr: ≥2.8mm, 8.5Fr: ≥3.2mm, 10Fr: ≥3.7mm, 11.5Fr ≥4.2mm	Similar
Guidewire	0.035"	0.035"	SE
Applicable Body Parts	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	SE
Operation Principle	The plastic stent is loaded on the introducer, and then advance the introducer and the plastic stent to the desired position in the human body through the preposition guide wire. After plastic stent reaching the desired position, release the plastic stent, and then withdraw the introducer.	The plastic stent is loaded on the introducer, and then advance the introducer and the plastic stent to the desired position in the human body through the preposition guide wire. After plastic stent reaching the desired position, release the plastic stent, and then withdraw the introducer.	SE
Surgical Technique	The plastic stent is visible under fluoroscopy, the radiopaque bands on the introducer are also visible under fluoroscopy. The plastic stent is placed within the body endoscopically using fluoroscopic monitoring.	The stent material is visible under fluoroscopy, the radiopaque bands on the introducer are also visible under fluoroscopy. The plastic stent is placed within the body endoscopically using fluoroscopic monitoring.	SE
Shelf Life	Conform to ASTM 1980	Conform to ASTM 1980	SE
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	SE
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	SE
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	SE

The proposed device is similar in design to predicate device cleared under K172044, which consists of plastic stent, introducer and system combines a plastic stent and an introducer.

The shapes and dimensions of proposed device are covered within the range of that of the predicate

device. All comparative non-clinical performance testing have been tested and have met the requirements of substantial equivalence to the predicate device.

Therefore, the difference between proposed device and predicated device is considered not to affect substantial equivalence between the proposed and predicate devices concerning safety and effectiveness.

8. Performance Data

The biocompatibility evaluation for the Biliary Plastic Stent Set 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:

Biocompatibility Testing to the plastic stent:

a) Cytotoxicity
b) Sensitization
c) Irritation
d) Acute Systemic Toxicity
e) Material Mediated Pyrogen
f) Implantation
g) Chemical Characterization and Biological Risk Assessment

Biocompatibility Testing to the introducer:

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

The following tests were conducted and evaluated for the subject device:

a) Dimension Testing

b) Deformation Recovery Testing

c) Flow Rate Testing

d) Plastic Stent Strength Testing

e) Retention Strength Testing

f) Introducer System Patency Testing

g) Introducer System Breaking Force Testing

h) Corrosion Testing

i) Visibility Under X-Ray Testing

j) Plastic Stent Release Testing

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. 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”.

The results of all the performance testing demonstrated that the proposed device met the acceptance criteria and support substantial equivalence to the predicate device cleared under K172044.

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 **proposed device** has been shown to be appropriate for its intended use and is substantially equivalent to the currently cleared predicate device **under K172044**.