March 29, 2022

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

Re: K220247
Trade/Device Name: Guidewire Locking Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: January 20, 2022
Received: January 28, 2022

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,

Shanil P. Haugen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220247

Device Name
Guidewire Locking Device

Indications for Use *(Describe)*
The Guidewire Locking Device is an accessory to be used with endoscopic biliary devices to lock the guidewire(s) in place during ERCP procedures.

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.

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: K220247

1. Date of Preparation: 2022-1-20

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 Engineer

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Email: RA.Micro-Tech@outlook.com

3. Identification of Proposed Device

Product Name: Guidewire Locking Device

Common Name: Locking Device

Regulatory Information

Classification Name: Endoscope and accessories.

Classification: 2

Product Code: ODC

Regulation Number: 876.1500

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K040137

Product Name in Original 510(k) Submission: Wilson-Cook USW Cap and Wire Lock

Current Trade Name in Market: Fusion Wire Guide Locking Device

Manufacturer: Wilson-Cook Medical Inc

5. Indications for Use

The Guidewire Locking Device is an accessory to be used with endoscopic biliary devices to lock the guidewire(s) in place during ERCP procedures.

6. Device Description

The Guidewire Locking Device is a sterile, single-use accessory to be used with endoscopic biliary devices, intended to be used to lock the wire guide(s) in place during ERCP procedures.

The Guidewire Locking Device is fitted on the duodenoscope to lock the guidewire and plug the working channel access. During the ERCP operation, the device and guidewire can be inserted into the endoscope through the opening of the guidewire locking device, the Guidewire Locking Device can lock up to two guidewires at the same time. During the insertion and exchange of the device, the guidewire can be locked and will not be moved, so the convenience of the operation can be improved.

The Guidewire Locking Device is composed with the guidewire locking assembly and the clamp seal assembly. The main materials of the proposed device include ABS, Silicone rubber, SUS304 and Polyurethane sponge.

This device should only be used by healthcare professional trained in ERCP. As an accessory of digestive endoscopy, the product shall be used by professionals familiar with the operation technique of digestive endoscopy.

There are 2 specifications which mainly differ in adaptive endoscope. MT-RGL-O-N is compatible for Olympus/ Fujinon Duodenoscope, and MT-RGL-P-N is compatible for Pentax Duodenoscope.

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 6 months.

7. Comparison of Technological Characteristics

The proposed device Guidewire Locking Device incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Fusion Wire Guide Locking Device.

Comparison between the proposed device and predicate device:

Item	Proposed Device **Guidewire Locking Device**	Predicate Device **Fusion Wire Guide Locking Device (K040137)**	Remark
Supplied in sterile	YES	YES	SE
Configuration	The guidewire locking assembly and the clamp seal assembly	The guidewire locking assembly and the clamp seal assembly	SE
Main Material	Main body: ABS	Plastic, unknown formulation	Similar
	Seal Cap :Silicone rubber	Rubber, unknown formulation	
Using Environment	Endoscopic Clinic	Endoscopic Clinic	SE
Compatible Endoscopy	Olympus/ Fujinon, Pentax	Olympus/ Fujinon, Pentax	SE
Indications for Use	The Guidewire Locking Device is an accessory to be used with endoscopic biliary devices to lock the guidewire(s) in place during ERCP procedures.	The Wilson-Cook USW Cap and Wire Lock Device is an accessory to be used with endoscopic biliary devices to lock the wire guide(s) in place during ERCP procedures.	SE
Mechanics of Action	Manual	Manual	SE
Multiple Locking Positions	Yes	Yes	SE
Single Use	Yes	Yes	SE
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Sterilization	EO Sterilized, SAL: 10^{-6}	EO Sterilized, SAL: 10^{-6}	SE

510k summary

Item	Proposed Device **Guidewire Locking Device**	Predicate Device **Fusion Wire Guide Locking Device (K040137)**	Remark
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	SE

8. Performance Data

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. Additionally, the results of the tests below were evaluated as substantially equivalent to the predicate device.

- Slide Block Flexibility Test
- Locking Retention Performance Test
- Friction Resistance Test
- Smoothness of Instrument Insertion Test
- Sealability Test
- Wire Locking Force Test
- Brush and Squeegee Performance Test
- Connection Force Test

Shelf-life 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. 6 months aging test was 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”.

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO-10993 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a

risk management process" issued on September 4, 2020. Biocompatibility testing included the following tests:

- ISO 10993-5: 2009 Biological evaluation of medical devices – Part5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices. Tests for irritation and sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

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 proposed device **Guidewire Locking Device** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **Fusion Wire Guide Locking Device (K040137).**