October 15, 2018

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

Re: K180418
Trade/Device Name: Reliant(TM) Multistage Dilatation Balloon Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE, KNQ
Dated: August 9, 2018
Received: August 13, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Jeffrey W. Cooper -S
2018.10.15 18:30:40 -04'00'

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)*
K180418

Device Name
Reliant(TM) Multistage Dilatation Balloon Catheter

Indications for Use *(Describe)*
The Reliant(TM) Multistage Dilatation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.

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.

1. Date of Preparation: 2018-10-10

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC
Establishment Registration Number: 3004837686
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Tel: +86-25-58646378
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Email: Beckyli_mt@outlook.com

3. Identification of Proposed Device

Product Name: Reliant™ Multistage Dilatation Balloon Catheter
Common Name: Reliant™ Multistage Dilatation Balloon Catheter
Regulatory Information
Classification Name: Biliary catheter and accessories
Classification: 2
Product Code: 1) FGE, 2) KNQ
Regulation Number: 876.5010
Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K162226
Product Name: Reliant™ Multistage Dilatation Balloon Catheter
Common Name: Reliant™ Multistage Dilatation Balloon Catheter
Regulatory Information
Classification Name: Biliary catheter and accessories
Classification: 2
Product Code: 1) FGE, 2) KNQ
Regulation Number: 876.5010
Manufacturer: Micro-Tech (Nanjing) Co., Ltd.

Review Panel: Gastroenterology/Urology
This predicate device has not been subject to a design-related recall.

5. Indications for Use

The Reliant™ Multistage Dilatation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.

6. Device Description

The Reliant™ Multistage Dilatation Balloon Catheter is capable of **3** distinct and progressively larger size diameters via controlled radial expansion. Specific balloon sizes are printed on each package and hub label.

The Reliant™ Multistage Dilatation Balloon Catheter is designed to pass through a 2.8mm or greater working channel of an endoscope. It will also accept a 0.035 inch (0.89 mm) guidewire through its guidewire lumen. This catheter comes packaged with a 0.035 inch (0.89mm) guidewire preloaded in the guidewire lumen. The guidewire is about 20cm longer than the balloon catheter with the excess length extending from single lumen tube.

The guidewire locking device is attached to the guidewire hub of the catheter. The locking device will be packaged in locked.

7. Comparison of Technological Characteristics

The Reliant™ Multistage Dilatation Balloon Catheter incorporates substantially equivalent device design, catheter configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices.

Comparison to Predicate Devices:

Item	Proposed Device	Predicate Device	Comparison
Product Code	1) FGE, 2) KNQ	1) FGE, 2) KNQ	Same
Regulation No.	1) 876.5010, 2) 876.5365	1) 876.5010, 2) 876.5365	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Same
Balloon Diameter (mm)	6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20	6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20	Same
Balloon length (mm)	30, 55, 80.	30, 55, 80.	Same

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510K Summary

Item	Proposed Device	Predicate Device	Comparison
Rated pressure(atm)	3-6-10, 3-5.5-9, 3-5-8,3-4.5-8,3-4.5-7,3-4.5-6	3-6-10, 3-5.5-9, 3-5-8,3-4.5-8,3-4.5-7,3-4.5-6	Same
Working Length（mm）	1800, 2300	1800, 2300	Same
Indications for Use	The Reliant™ Multistage Dilitation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.	The Reliant™ Multistage Dilitation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.	Same
Configuration	Tip, balloon, marker band, handle junction, and guidewire.	Tip, balloon, marker band, handle junction, and guidewire.	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	Three years (36 months)	Three years (36 months)	Same

The modifications that were made are as follows:

- Add silicone spray to the surface of balloon
- Labelling change
- Package material change

8. Performance Data

Risk analysis was carried out in accordance with established in-house acceptance criteria based on AAMI / ANSI / ISO 14971:2007/(R) 2010 (Corrected 4 October 2007), Medical Devices - Applications of Risk Management to Medical Devices. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Comparison to Predicate Device K162226, the modifications that were made are as follows:

- Add silicone spray to the surface of balloon
- Labelling change
- Package material change

All necessary verification and validation tests have been performed on the proposed device to assure substantial equivalence to the predicate device. The tests include:

Balloon Appearance Test	Endoscopic Compatibility Test
Retraction Test	Balloon Burst Pressure Test
Tensile Strength Testing Test	Balloon Fatigue Testing Test
Balloon Inflation and Deflation Test	Radiopacity Test
Dimension Test	Biocompatibility Evaluation
EO Residual Test	ECH Residual Test
Sterility Test	Package Integrity Test

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 Reliant™ Multistage Dilatation Balloon Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Predicate Devices.