



Food and Drug Administration
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October 16, 2015

Micro-Tech (Nanjing) CO., Ltd.
Becky Li
Quality Manager
No.10 Gaoke Third Rd., Nanjing National Hi-Tech
Industrial Development Zone
Nanjing, Jiangsu 210032
China

Re: K151671
Trade/Device Name: Disposable Multistage Dilation Balloon Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE, KNQ
Dated: September 6, 2015
Received: September 10, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)
K151671

Device Name
Disposable Multistage Dilation Balloon Catheter

Indications for Use (Describe)

The Disposable Multistage Dilation 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.

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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: K151671

1. Date of Preparation: 10/14/2015

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

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3. Identification of Proposed Device

Product Name: Disposable Multistage Dilation Balloon Catheter

Common Name: Disposable Multistage Dilation Balloon Catheter

Regulatory Information

Classification Name: 1) Catheter, Biliary, diagnostic, 2) Dilator, esophageal

Classification: 2

Product Code: 1) FGE, 2) KNQ

Regulation Number: 1) 876.5010, 2) 876.3565

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K112994

Trade Name: *CRE Dilatation Balloon*

Common Name: CRE Wireguided Dilatation Balloon

5. Indications for Use

The Disposable Multistage Dilation Balloon Catheter is indicated for use in



adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.

6. Device Description

The **Disposable Multistage Dilation 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 **Disposable Multistage Dilation Balloon Catheter** is designed to pass through a 2.8mm or greater working channel of an endoscope. It will also accept a 0.035 in (0.89 mm) guidewire through its guidewire lumen. This catheter comes packaged with a 0.035 in (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 **Disposable Multistage Dilation Balloon Catheter** incorporates substantially equivalent device materials, design, catheter configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate devices.

Comparison to predicate Devices:

Item	Proposed Device Disposable Multistage Dilation Balloon Catheter	Comparison to Predicate Devices
Product Code	1) FGE, 2) KNQ	Similar
Regulation No.	1) 876.5010, 2) 876.3565	Similar
Class	2	Same
Supplied Sterile	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	Same
Balloon length (mm)	30, 55, 80.	Similar
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	Same
Working Length (mm)	1800, 2300	Similar



Item	Proposed Device Disposable Multistage Dilation Balloon Catheter	Comparison to Predicate Devices
Indications for Use	The Disposable Multistage Dilation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.	Similar
Configuration	Tip, balloon, marker band, handle junction, and guidewire.	Similar
Single Use	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Similar
Shelf Life	Three years (36 months)	Similar

8. Performance Data

Bench testing was performed to support a determination of substantial equivalence. The Disposable Multistage Dilation Balloon Catheter performs as well as the predicate and is substantially equivalent to the predicate devices. The following in-vitro performance tests were completed on the **Disposable Multistage Dilation Balloon Catheter**:

Balloon Diameter	Endoscopic Compatibility Testing
Balloon length	Balloon Burst Pressure
Rated pressure	Balloon Fatigue Testing
Working Length	Radiopacity
Retraction testing	Balloon Inflation/Deflation Testing
Tensile Strength	Package integrity
Tip Pull Testing	Shelf Life Testing

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 **Disposable Multistage Dilation Balloon Catheter** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific CRE Wireguided Dilatation Balloon.