January 25, 2017

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

Re: K162226
Trade/Device Name: Reliant™ Multistage Dilatation Balloon Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE, KNQ
Dated: December 27, 2016
Received: December 27, 2016

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,

Charles Viviano -S

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
Indications for Use

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."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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: 2016-12-15

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
Contact Person: Becky Li
Position: Quality Director
Tel: +86-25-58646378
Fax: +86-25-58744269
Email: In@micro-tech.com.cn

3. Identification of Proposed Device
Product Name: Reliant™ Multistage Dilatation Balloon Catheter
Common Name: Reliant™ Multistage Dilatation 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: K151671
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) 876.5365
Manufacture: 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 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 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 device.

Comparison to Predicate Devices:

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed Device</th>
<th>Predicate Device (K151671)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code</td>
<td>1) FGE, 2) KNQ</td>
<td>1) FGE, 2) KNQ</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>1) 876.5010, 2) 876.5365</td>
<td>1) 876.5010, 2) 876.5365</td>
<td>Same</td>
</tr>
<tr>
<td>Class</td>
<td>2</td>
<td>2</td>
<td>Same</td>
</tr>
<tr>
<td>Supplied Sterile</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Balloon Diameter (mm)</td>
<td>6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20</td>
<td>6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20</td>
<td>Same</td>
</tr>
<tr>
<td>Item</td>
<td>Proposed Device</td>
<td>Predicate Device (K151671)</td>
<td>Comparison</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------</td>
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<td>------------</td>
</tr>
<tr>
<td>Balloon length (mm)</td>
<td>30, 55, 80.</td>
<td>30, 55, 80.</td>
<td>Same</td>
</tr>
<tr>
<td>Rated pressure(atm)</td>
<td>3-6-10, 3-5.5-9,</td>
<td>3-6-10, 3-5.5-9,</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>3-5-8.3-4.5-8.3-4.5-7.3-4</td>
<td>3-5-8.3-4.5-8.3-4.5-7.3-4.5-6</td>
<td></td>
</tr>
<tr>
<td>Working Length (mm)</td>
<td>1800, 2300</td>
<td>1800, 2300</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Reliant™ Multistage Dilitation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.</td>
<td>The Disposable Multistage Dilation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.</td>
<td>Same</td>
</tr>
<tr>
<td>Configuration</td>
<td>Tip, balloon, marker band, handle junction, and guidewire.</td>
<td>Tip, balloon, marker band, handle junction, and guidewire.</td>
<td>Same</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Single-use EO sterilized pouch with one device per pouch</td>
<td>Single-use EO sterilized pouch with one device per pouch</td>
<td>Same</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>Three years (36 months)</td>
<td>Three years (36 months)</td>
<td>Same</td>
</tr>
<tr>
<td>Tensile Strength between Balloon and Double Lumen Tube(N)</td>
<td>67.11±2.16</td>
<td>78.11±9.59</td>
<td>Similar</td>
</tr>
<tr>
<td>Tensile Strength between Double Lumen Tube and Junction(N)</td>
<td>109.99±2.12</td>
<td>94.67±3.54</td>
<td>Similar</td>
</tr>
<tr>
<td>Biocompatibility-Cytotoxicity</td>
<td>The test article extracts had not a cytotoxic potential.</td>
<td>The test article extracts had not a cytotoxic potential.</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility-Sensitization</td>
<td>Neither SC extracts nor CSO extracts of the test article had evidence of causing sensitization in the guinea pig.</td>
<td>Neither SC extracts nor CSO extracts of the test article had evidence of causing sensitization in the guinea pig.</td>
<td>Same</td>
</tr>
<tr>
<td>Item</td>
<td>Proposed Device</td>
<td>Predicate Device (K151671)</td>
<td>Comparison</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Biocompatibility-Irritation</td>
<td>The test article extracts have no animal intracutaneous reactivity as compared to the control.</td>
<td>The test article extracts have no animal intracutaneous reactivity as compared to the control.</td>
<td>Same</td>
</tr>
</tbody>
</table>

8. Performance Data

The modifications that were made include:

- Double lumen tube is modified due to change the tubing material.
- The product name is changed slightly.

Comparison to Predicate Devices K151671, the material of double lumen tube is changed, according by FMEA, all necessary verification and validation tests have been performed for the Reliant™ Multistage Dilatation Balloon Catheter to assure substantial equivalence to the predicate device.

- Tensile Strength between Balloon and Double Lumen Tube
- Tensile Strength between Double Lumen Tube and Junction
- Biocompatibility Test

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the indications for use and technological characteristics, substantially equivalent to the predicate device, the Reliant™ Multistage Dilatation Balloon Catheter is considered to be substantially equivalent to the Predicate Device (K151671 Disposable Multistage Dilation Balloon Catheter).