May 5, 2017

Teleflex Medical, Inc.
Lori Pfohl
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re:  K161770
    Trade/Device Name: Rusch Silicone Foley Catheter
    Regulation Number: 21 CFR§ 876.5130
    Regulation Name: Urological Catheter and Accessories
    Regulatory Class: II
    Product Code: EZL
    Dated: April 6, 2017
    Received: April 7, 2017

Dear Lori Pfohl:

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,

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)
K161770

Device Name
Rusch Silicone Foley Catheter

Indications for Use (Describe)
The Rusch Brilliant Balloon Catheter is indicated for routine transurethral drainage of the bladder.

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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510(k) SUMMARY

Rusch Silicone Foley Catheter

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-491-8960
Fax: 919-433-4996

Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

Date Prepared

4/5/2017

Device Name

Trade Name: Rusch Silicone Foley Catheter
Common Name: Disposable Balloon-Retention Catheter
Classification Name: Catheter, Retention Type, Balloon (Class II per 21 CFR 876.5130, Product Code EZL)

Predicate Device

Guangdong Baihe Medical Technology Co., Ltd. - K130908

Device Description

The Rusch Silicone Foley Catheter is a balloon retention type catheter and is single use, disposable and sterile. The retention balloon is attached to the silicone two-lumen shaft. One lumen is used for drainage and the other lumen for inflation and deflation of the balloon. Sterile water is used to inflate and deflate the balloon. The distal end has two opposite eye holes which are used for drainage. On the opposing end of the shaft are a connective funnel and a Luer activated valve.

Indications for Use

The Rusch Brilliant Balloon Catheter is indicated for routine transurethral drainage of the bladder

Intended Population: Pediatric
Contraindications
- Insurmountable urethral passages
- Excessive urethral stricture via falsa

Substantial Equivalence
The subject device is substantially equivalent to the predicate devices:

<table>
<thead>
<tr>
<th>Features</th>
<th>Teleflex Medical Rusch Silicone Foley Catheter (Subject Device)</th>
<th>Guangdong Baihe Medical Technology Co., Ltd. (Predicate Device-K130908)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification Name</td>
<td>Catheter, Retention Type, Balloon</td>
<td>Same</td>
</tr>
<tr>
<td>Product Code</td>
<td>EZL</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>876.5130</td>
<td>Same</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
<td>Same</td>
</tr>
</tbody>
</table>
| Indications for Use       | The Rusch Brilliant Balloon Catheter is indicated for routine transurethral drainage of the bladder | Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; indwelling time of the proposed device is no more than 30 days.  
Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; indwelling time of the proposed device is no more than 30 days. |
| Population                | Pediatric, Male and female                                       | Same                                                                   |
| Lumen                     | Two-Way                                                          | Two way and three way                                                  |
| Indwell Time              | Maximum indwell time of 29 days                                  | No more than 30 days                                                  |
| Single Use                | Yes                                                              | Same                                                                   |
| Size Range                | 6Fr                                                              | 6-26Fr                                                                 |
| Length                    | 300 ±10mm                                                        | 310mm and 400mm                                                       |
| Balloon                   | Yes                                                              | Same                                                                   |
| Balloon size              | 1.5ml                                                            | Same                                                                   |
| Sterile                   | Yes                                                              | Same                                                                   |
| Method of Sterilization   | Ethylene Oxide 10^{-6} SAL                                       | Same                                                                   |
| Biocompatibility          | Materials have been tested per ISO 10993                       | Same                                                                   |
| Main Shaft Material       | Silicone                                                         | Same                                                                   |
| Eyes in Tip               | Yes                                                              | Same                                                                   |
| Standard Funnel           | Yes                                                              | Same                                                                   |
| Tip Shape                 | Rounded                                                          | Same                                                                   |
The subject device is substantially equivalent to the subject device and nonclinical test data demonstrates substantial equivalence.

Non-clinical Performance testing

The bench testing performed verifies that the performance of the subject Rusch Silicone Foley Catheter is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include Balloon Peel Strength, Balloon Security, Deflation Reliability, Shaft Pull Test, Tip Detachment, and Funnel Detachment.

Conclusion

The Rusch Silicone Foley Catheter has the same indications for use, technological characteristics and construction as its predicates. Performance test results demonstrate that the subject device meets its intended use. It is for these reasons that the subject device can be found substantially equivalent.