DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 24, 2017

Teleflex Medical, Inc.
Lori Pfohl
Senior Regulatory Affairs Specialist
3015 Carrington Mills Blvd
Morrisville, North Carolina 27560

Re: K162989
Trade/Device Name: Rusch Simplastic Foley Catheters
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: Class II
Product Code: EZL
Dated: February 1, 2017
Received: February 6, 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,

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

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)*
K162989

Device Name
Rusch Simplastic Foley Catheters

Indications for Use *(Describe)*
These catheters are indicated for routine transurethral drainage of the bladder or for routine post-operative transurethral drainage and irrigation 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 Simplastic Foley Catheters

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919-491-8960

Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

Date Prepared

1/23/2017

Device Name

Trade Name: **Rusch Simplastic Foley Catheters**

Common Name: Disposable Balloon-Retention Catheter

Classification Name: Catheter, Retention Type, Balloon (Class II per 21 CFR 876.5130, Product Code EZL)

Predicate Devices

Rusch Simplastic Foley Catheterization Set – K963996
Amsino International Amsure Hydrophilic Latex Foley Catheter (K091699)

Device Description

The **Rusch Simplastic Foley Catheter** is a balloon retention type catheter and is single use, disposable and sterile. The catheters are made of transparent PVC. They have a 2 lumen or 3 lumen shaft with proximal funnel, inflation valve and a distal retaining balloon made of latex. Balloon capacity is in ml and the shaft size in French gauge (Fr.) as indicated on the funnel of each individual catheter.

Indications for Use

These catheters are indicated for routine transurethral drainage of the bladder or for routine post-operative transurethral drainage and irrigation of the bladder.

510(k) SUMMARY

Rusch Simplastic Foley Catheters

Substantial Equivalence

The subject device is substantially equivalent to the predicate devices:

Features	Teleflex Medical Rusch Simplastic Foley Catheters (Subject Device)	Rusch Simplastic Foley Catheterization Set (Predicate Device- K963993)	Amsino International Amsure Hydrophilic Latex Foley Catheter (K091699)
Classification Name	Catheter, Retention Type, Balloon	Tray, Catheterization, Sterile urethral, With Or Without Catheter	Catheter, Retention Type, Balloon
Product Code	EZL	FCM	EZL
Regulation Number	876.5130	Same	Same
Class	II	Same	Same
Indications for Use	These catheters are indicated for routine transurethral drainage of the bladder or for routine post-operative transurethral drainage and irrigation of the bladder.	The Rusch Simplastic Foley Catheter is intended to be used to pass fluid to and from the urinary tract. A pack of lubricating jelly is intended to assist insertion of the catheter through the urethra.	The Amsure Hydrophilic Latex Foley Catheter, is intended for use in the drainage of fluids from, and to the urinary tract/bladder
Population	Adult and Pediatric	Not Specified	Adult and Pediatric
Lumen	Two way and three way	Same	Not specified
Single Use	Yes	Same	Same
Size Range	12-28Fr	12-26Fr	12-28
Radiopaque	Yes	Same	Not Specified
Balloon Sizes	30 and 75 ml	10, 30 and 75ml	5 and 30 ml
Balloon Material	Latex	same	Same
Shaft Material	PVC	PVC	Silicone coated natural latex
Coated or Uncoated	Uncoated	Uncoated	Coated
Connections	Luer Taper/Funnel	Same	Same
Biocompatibility	Materials have been tested per ISO 10993	Same	Not Specified
Sterile	Yes	Same	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide or Gamma	Same

The subject device is substantially equivalent to the subject device and nonclinical test data demonstrates substantial equivalence.

510(k) SUMMARY

Rusch Simplastic Foley Catheters

Non-clinical Performance testing

The bench testing performed verifies that the performance of the subject device 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, and Funnel Detachment.

Conclusion

The **Rusch Simplastic 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.