July 27, 2023

Teleflex Medical, Inc.
Kelley Breheim
Sr. MDR Regulatory Project Manager
3015 Carrington Mill Blvd.
Morrisville, NC 27560

Re: K212077
Trade/Device Name: Rusch SoftSimplastic Foley Catheters
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: June 23, 2023
Received: June 23, 2023

Dear Kelley Breheim:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212077

Device Name
Rusch SoftSimplastic Foley Catheters

Indications for Use *(Describe)*

2 Way SoftSimplastic Catheters:
Indicated where routine transurethral drainage of the bladder is required either postoperatively or for patients with conditions requiring transurethral urine drainage.

3 Way SoftSimplastic Catheters:
Indicated where routine transurethral drainage of the bladder is required either postoperatively, for patients with conditions requiring transurethral urine drainage and for patients requiring bladder irrigation.

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

[As required by 21 CFR 807.92]

Date Prepared: July 26, 2023

510(k) Number: K212077

Submitter's Name / Contact Person

Manufacturer
Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 612-500-1344

Contact Person
Kelley Breheim
Sr. MDR Regulatory Project Manager

General Information

Trade Name:	Rusch SoftSimplastic Foley Catheters
Common / Usual Name:	Disposable Balloon-Retention Catheter
Classification Name:	Urological Catheter and Accessories
Regulation Number:	21 CFR 876.5130
Product Code:	EZL
Device Class:	Class II
Predicate Device	K162989, Rusch Simplastic Foley Catheters. This predicate device has not been subject to a design-related recall.

Device Description

The Rusch SoftSimplastic 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.

Product Codes	Size (Fr)	Product Description
4426/662430	14 – 24	SoftSimplastic 2 Way 30ml Catheter Coude/Mercier Tip
5706/664130	16 – 24	SoftSimplastic 3 Way 30ml Catheter Couvelaire Tip
5707/662530	16 – 24	SoftSimplastic 2 Way 30ml Catheter Couvelaire Tip
5708/664176	18 – 24	SoftSimplastic 3 Way 75ml Catheter Couvelaire Tip

Indications for Use

2 Way SoftSimplastic Catheters:
Indicated where routine transurethral drainage of the bladder is required either postoperatively or for patients with conditions requiring transurethral urine drainage.

3 Way SoftSimplastic Catheters:
Indicated where routine transurethral drainage of the bladder is required either postoperatively, for patients with conditions requiring transurethral urine drainage and for patients requiring bladder irrigation.

Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics between the Rusch SoftSimplastic Foley Catheters and the predicate device are provided in the following table.

Comparison of Technological Characteristics		
Characteristic	**Subject Device**	**Primary Predicate Device**
	Rusch SoftSimplastic Foley Catheters	**Rusch Simplastic Foley Catheters**
Classification Name	Catheter, Retention Type, Balloon	Catheter, Retention Type, Balloon
Product Code	EZL	EZL
Regulation Number	876.5130	876.5130
Class	II	II

Indications for Use	2 Way SoftSimplastic Catheters: Indicated where routine transurethral drainage of the bladder is required either postoperatively or for patients with conditions requiring transurethral urine drainage. 3 Way SoftSimplastic Catheters: Indicated where routine transurethral drainage of the bladder is required either postoperatively, for patients with conditions requiring transurethral urine drainage and for patients requiring bladder irrigation.	These catheters are indicated for routine transurethral drainage of the bladder or for routine post-operative transurethral drainage and irrigation of the bladder.

Comparison of Technological Characteristics		
Characteristic	**Subject Device**	**Primary Predicate Device**
	Rusch SoftSimplastic Foley Catheters	**Rusch Simplastic Foley Catheters**
Shelf Life	5 Year	1 Year
Size Range	14-24Fr	12-28Fr
Balloon Sizes	30 and 75 ml	30 and 75 ml
Balloon Material	Latex	Latex
Shaft Material	PVC with dioctyl terephthalate (DOTP) plasticizer	PVC with bis(2-ethylhexyl) phthalate (DEHP) plasticizer
Connections	Luer Taper/Funnel	Luer Taper/Funnel
Lumen	Two way and three way	Two way and three way
Population	Adult	Adult and Pediatric

Biocompatibility	Materials have been tested per ISO 10993	Materials have been tested per ISO 10993
Sterile	Yes	Yes
Method of Sterilization	Ethylene Oxide	Ethylene Oxide
Single Use or Reusable	Single Use	Single Use
Coated or Uncoated	Uncoated	Uncoated
Radiopacity	Yes	Yes

In this 510(k), the sponsor proposed modifications to their previously cleared device, including a material change, an extension of shelf-life and minor labeling changes. Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

Biocompatibility

The biocompatibility evaluation for the Rusch SoftSimplastic Foley Catheters was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Test	Standard
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Intracutaneous Reactivity	ISO 10993-23
Bacterial Reverse Mutation Assay (ISO)	ISO 10993-3
Acute Systemic Toxicity Test (ISO)	ISO 10993-11
Material Mediated Pyrogenicity Test (ISO/USP)	ISO 10993-11
Mouse Lymphoma Assay (ISO)	ISO 10993-3
Implantation Test (ISO)	ISO 10993-6
28-Day Systemic Toxicity (Dual Route Repeated Exposure Method) Test (ISO)	ISO 10993-11

Performance - Bench

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. The following table of test methods and standards (including packaging and sterility) were relied upon for a determination of substantial equivalence.

Test	Reference to Standard (if applicable)
Visual inspection - Shaft	ISO 20696:2018
Visual inspection - Balloon	ISO 20696:2018
Visual inspection - Funnel	ISO 20696:2018
Visual inspection - Tip	ISO 20696:2018
Effective Shaft Length	ISO 20696:2018
Strength of Catheter	ISO 20696:2018
Connector Security	ISO 20696:2018
Balloon Safety	ISO 20696:2018
Inflation and Deflation Test	ISO 20696:2018
Flow Rate Through Catheter	ISO 20696:2018
Kink Stability	ISO 20696:2018
Peak Tensile Force - Shaft	ISO 20696:2018
Peak Tensile Force - Funnel	ISO 20696:2018
Peak Tensile Force - Balloon	ISO 20696:2018
Peak Tensile Force - Tip	ISO 20696:2018
Inflated Balloon Response to Traction	ISO 20696:2018
Flow Rate Through Drainage Lumen	ASTM F623-99
Balloon Integrity (Resistance to Rupture)	ASTM F623-99
Inflated Balloon Response to Traction	ASTM F623-99
Balloon Volume Maintenance	ASTM F623-99
Balloon and Shaft Size	ASTM F623-99
Deflation Reliability	ASTM F623-99
Radiopacity	ASTM F640-12
Ethylene Oxide Sterilization	ISO 11135-1
EO Residuals	ISO 10993-7
Packaging	ISO 11607-1 ISO 11607-2 ASTM D4169 ASTM F1886/F1886M ASTM F88/F88M EN 868-5 ASTM F2096

Conclusion

The Rusch SoftSimplastic Foley Catheter has the same intended use, technological characteristics, and construction as its predicate, with the exception of different PVC plasticizer material. Performance test results demonstrate that the subject device is as safe and effective as the predicate device. The Rusch SoftSimplastic Foley Catheter is substantially equivalent to the predicate device.