May 8, 2019

Teleflex Medical, Inc.
Lori Pfohl
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd., Suite 600 North
Morrisville, NC 27560

Re: K183461
Trade/Device Name: Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles)
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: April 5, 2019
Received: April 8, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Acting, Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183461

Device Name
Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles).

Indications for Use *(Describe)*

The Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are tubular devices that are inserted through the urethra to pass urine from 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.

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."

510(k) Summary

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560
Phone: 919-433-4831
Fax: 919-361-3939

B. Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

C. Date Prepared

May 7, 2019

D. Device Name

Trade Name: Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles)

Common Name:	Catheter, Urethral
Product Code:	GBM
Regulation Number:	CFR 876.5130
Classification Name:	Urological catheter and accessories
Classification:	II
Classification Panel:	Gastroenterology/Urology

E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device:

Rusch® FloCath – K000070

F. Device Description

The Teleflex Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are single use, disposable and sterile. The catheters are made of clear

polyvinylchloride (PVC) with vertically cut and softly rounded polished eyes and are coated with a hydrophilic coating. They are composed of a shaft with a proximal funnel and a tip. The funnel is made of PVC. The shaft size ranges from 6-20 French gauge. The funnel is color coded to facilitate size identification. The **Rusch® FloCath™ Quick** is an "all-in-one catheter" that allows for convenience and the **Rusch® MMG H2O™** is a closed system with integrated collection bag that allows for "no touch" catheterization due to an introducer tip that helps bypass the first 1.5" of the urethra.

G. Indications for Use

The Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are tubular devices that are inserted through the urethra to pass urine from the bladder.

H. Contraindications

- Insurmountable urethral obstructions
- Urethral injuries
- Urethral inflammation

I. Substantial Equivalence

The subject device Teleflex Rusch FloCath Quick Hydrophilic Intermittent Catheter is substantially equivalent to the predicate devices with respect to intended use, technology and construction. The differences between the predicates and the subject devices are minor and any risks have been mitigated through testing. **Table 07.1** summarizes the differences between the subject and predicate device.

The subject devices are substantially equivalent to the predicate device:

Table 07.1 - Comparison of Predicate vs. Subject Devices

Features	Teleflex Medical Rusch FloCath Quick Urological Catheter (Subject Devices 1)	Teleflex Medical Rusch MMG Urological Catheter (Subject Device 2)	Rusch FloCath – Uncoated or Coated Urological Catheter (Predicate Device-K000070)
Classification Name	Urological Catheter and Accessories	Same	Same
Regulation Number	876.5130	876.5130	Same
FDA Procode	GBM	GBM	KOD
Class	II	II	Same
Indication for Use	The Rusch Hydrophilic Intermittent	The Rusch Hydrophilic Intermittent catheters (Rusch	The FloCath catheter is a tubular device that is inserted through the urethra

	catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are tubular devices that are inserted through the urethra to pass urine from the bladder.	FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are tubular devices that are inserted through the urethra to pass urine from the bladder.	and is used to pass fluids to or from urinary tracts.
Contraindications	- Insurmountable urethral obstructions- Urethral injuries- Urethral inflammation	None	None
Single Use	Yes	Yes	Same
Population	Adult and Pediatric, Male and Female	Adult and Pediatric, Male and Female	Same
Size Range	6-20 Fr.	6-20 Fr.	5-30 Fr.
Overall Length	40 cm	40cm	Same
Shaft	Tubular	Tubular	Same
Shaft Material	PVC (Mucosal and skin, limited contact <24hr)	PVC (Mucosal and skin, limited contact <24hr)	Same
Coating	Hydrophilic	Hydrophilic	Uncoated or Hydrogel/ Hydrophilic Coating
Biocompatibility	Evaluation and testing within the risk management process ISO 10993-1: Cytotoxicity ISO 10993-5 Sensitization ISO 10993-10 Skin Irritation ISO 10993-10	Evaluation and testing within the risk management process ISO 10993-1: Cytotoxicity ISO 10993-5 Sensitization ISO 10993-10 Skin Irritation ISO 10993-10	Same
Tip	Nelaton, Olive, or Tiemann tip	Split introducer, introducer tip, and cap	Nelaton, Olive, or Tiemann tip
Eyelets	Yes	Yes	Yes
Liquid for Wetting	0.9% Sterile saline	0.9% Sterile saline	Tap Water

	solution	solution	
Primary Packaging	Paper and film peel back	Paper and film peel back	Same
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf-life	5 Years	5 Years	Same

J. Comparison to the Predicate

Table 7.1 illustrates the similarities and differences between the subject and predicate device (K000070). The basic technological and operating principles are the same for both devices. Both the predicate and subject devices have same intended use.

Both the subject and predicate devices are intended for similar patient populations adult and pediatric, male and female. Both the subject and predicate devices are disposable, non-sterile, single patient use devices. As evidenced by comparison Table 7.1, above, the subject FloCath Quick Hydrophilic Intermittent Catheter is substantially equivalent to the predicate device. There are no significant differences that would affect safety and efficacy.

K. Performance Data

The bench testing performed verifies that the performance of the subject devices are substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Visual Inspection
- Flow Rate
- Friction Test
- Coating Presence
- Biocompatibility
    a. ISO 10993-1:2009 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
    b. ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity
    c. ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization

The testing performed verifies that the performance of the subject devices are substantially equivalent in terms of critical performance characteristics to the predicate device.

The subject devices were tested to the requirements of ASTM F623.

Cytotoxicity, Sensitization, Irritation, were performed to demonstrate biocompatibility of the patient contacting materials. Overall, the results are comparable to the predicate and support a determination of substantial equivalence.

L. Conclusion

The Rusch Hydrophilic Intermittent Catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are tubular devices that are inserted through the urethra to pass urine from the bladder.

The Rusch Hydrophilic Intermittent Catheters have the same intended use and technological characteristics as the predicate. Test results demonstrate that the subject devices meet their intended use and performs as well as or better than the legally marketed predicate device. It is for these reasons that the subject devices can be found substantially equivalent.