May 24, 2019

Teleflex Medical, Inc.
Sirisha Kommana
Regulatory Affairs Specialist
3015 Carrington Mill Blvd., Suite 600 North
Morrisville, NC 27560

Re: K181979
Trade/Device Name: Rusch FloCath Quick 18 Fr. Coudé Hydrophilic Intermittent Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: April 24, 2019
Received: April 26, 2019

Dear Sirisha Kommana:

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,

for Glenn B. Bell, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181979

Device Name

Rusch FloCath Quick 18 Fr. Coudé Hydrophilic Intermittent Catheter

Indications for Use *(Describe)*

The subject device is a tubular device that is 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.

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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

Sirisha Kommana
Regulatory Affairs Specialist, Respiratory Division

C. Date Prepared

May 23, 2019

D. Device Name

Trade Name:	Rusch FloCath Quick™ 18 Fr. Coudé Hydrophilic Intermittent Catheter
Common Name:	Catheter, Urethral
Product Code:	GBM
Regulation Number:	CFR 876.5130
Regulation 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® FloCath Quick™** 18 French (Fr.) Coudé Hydrophilic Intermittent Catheter is single use, disposable and sterile. The catheter is made of clear polyvinylchloride (PVC) with vertically cut and softly rounded, polished eyes and has a hydrophilic coating. It is composed of a shaft with a proximal funnel and a tip. The funnel is made of PVC. The shaft size is an 18 French gauge and is identified on the packaging. The funnel is color coded red to facilitate size identification. The catheter is 40 cm in overall length.

The **FloCath Quick** is an integrated package that contains the FloCath catheter with a blue protective catheter sleeve and a packet of sterile 0.9% saline. Before opening, the sterile saline pouch is broken to hydrate the catheter. The protective catheter sleeve allows for touchless insertion. The sleeve can also be pushed back and used as an extension to the catheter.

The **FloCath Quick** packaging has a packaging hole to facilitate opening the catheter. Either the packaging hole or the adhesive patch on the catheter pack can be used to hang up the catheter in an appropriate, convenient location while the catheter is hydrated.

G. Indications for Use

The Subject device is a tubular device that is inserted through the urethra to pass urine from the bladder.

H. Contraindications

- Insurmountable urethral obstructions
- Urethral injuries
- Urethral inflammation

I. Substantial Equivalence

The proposed Teleflex Rusch FloCath Quick 18 Fr. Coudé 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 proposed devices are minor and any risks have been mitigated through testing. **Table 036-1** summarizes the differences between the proposed and predicate devices.

The proposed device is substantially equivalent to the predicate device:

Table 36-1. Comparison of Predicate vs. Proposed Device

Features	Teleflex Medical Rusch FloCath Quick Urological Catheter (Subject Device)	Rusch FloCath (Predicate Device- K000070)
Classification Name	Catheter Urethral	Catheter Urological
Product Code	GBM	KOD
Class	II	II
Regulation Number	876.5130	876.5130
Single Use	Yes	Yes
Patient Population for 18 Fr.	Adult	Adult
Size Range	18 Fr.	5-30 Fr.
18 Fr. Overall Length	40 cm	40 cm
Color Indicating Size for 18 Fr.	Red	Red
Sterile	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide or Gamma irradiation.
Device Description	The FloCath Quick is a sterile, ready-to-use, flexible PVC catheter for intermittent catheterization. The catheter is hydrophilic coated and has an integrated pouch containing a 0.9% sterile saline solution and a handling sheath. The FloCath Quick is a Coudé, 18 Fr. Catheter.	The Rusch FloCath Catheter consists of a tubular PVC shaft with attached drainage funnel. The catheters is designed with either Nelaton, Olive or Tiemann tip. This device shaft may be uncoated or Hydrogel/ Hydrophilic coated.

Shaft	Tubular	Tubular
Shaft Material	PVC	PVC
Funnel Material	PVC	PVC
Intended Use	The FloCath Quick catheter is a tubular device that is inserted through the urethra and is used to pass fluids from urinary tract.	FloCath catheter is a tubular device that is inserted through the urethra and is used to pass fluids to or from urinary tracts.
Indication for Use	The subject device is a tubular device that is inserted through the urethra to pass urine from the bladder.	FloCath catheter is a tubular device that is inserted through the urethra and is used to pass fluids to or from urinary tracts.
Contraindications	• Insurmountable urethral obstructions • Urethral injuries • Urethral inflammation	None
Coating	Hydrophilic	Uncoated or Hydrogel/ Hydrophilic Coating
Materials Evaluation	The materials used in the construction of	The materials used in the construction of

	FloCath Quick were evaluated per ISO 10993-1:2009	predicate were evaluated per ISO 10993-5:1993, 10993-10:1995
Principle of Operation – Short Description of Use	Squeeze saline sachet. Move packaging up and down 2 or 3 times to ensure coating of the catheter. Hang and let soak for 30 seconds. Peel package open. Insert catheter using blue protective catheter sleeve. Empty bladder Withdraw catheter Dispose device	Tear peel back wrapper about 5cm. Pour water into catheter funnel. Takes about 30 seconds for catheter to activate. Remove catheter from the package by the funnel and insert the catheter. Empty bladder Withdraw catheter Dispose device
Eyelets	Yes	Yes
Liquid for Wetting	0.9% Sterile saline solution	Tap water
Primary Packaging	Paper and film peel back	Paper and film peel back
Secondary Packaging	Corrugated board	Corrugated board
Shipper Case	Corrugated board	Corrugated board
Shelf-life	5 Years	5 Years
Performance Standards	ASTM F623:2013 EN 1616:1997, EN 1617:1997, EN 1618:1997	ASTM F623-89

J. Comparison to the Predicate

Table 36-1 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 device have same intended use.

Both the subject and predicate device are intended for similar patient populations, adult. Both the subject and predicate devices are disposable, sterile, single use devices. As evidenced by comparison Table 7-1, above, the proposed FloCath Quick 18 Fr. Coudé 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 device FloCath Quick 18 Fr. Coudé Hydrophilic Intermittent Catheter is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

Testing Performed	Reference to Standard	Results
Visual Inspection	NA	Pass
Connector Security Test	EN 1616:1997	Pass
Instron Pull Test	EN 1617:1997 EN 1618:1997	Pass
Flow Rate	EN 1618:1997 ASTM F623:2013	Pass
Coating Presence	NA	Pass
Friction Test	NA	Pass
Biocompatibility Testing	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Pass
Sterilization	ISO 11135-1: 2014 ISO 11137-1: 2006	Pass

The proposed devices were tested to the requirements of EN 1616:1997, EN1617:1997, EN 1618:1997. In addition, testing was performed to ensure compliance to ASTM F623:2013.

Cytotoxicity, Sensitization, Irritation, were performed to demonstrate biocompatibility of the patient contacting materials.

The proposed device is sterilized using Ethylene Oxide method and the saline sachet is sterilized using Gamma Irradiation method. The respective sterilization validations performed are ETO overkill method and the dose audit study.

Overall, the results are comparable to the predicate and support a determination of substantial equivalence.

L. Conclusion

The **FloCath Quick** 18 Fr. Coudé Hydrophilic Intermittent Catheter has the same intended use and technological characteristics as its predicates. Test results demonstrate that the proposed device meets its intended use and is as safe, as effective, and performs as well as or better than the legally marketed predicate device. It is for these reasons that the subject device can be found substantially equivalent.