January 20, 2026

Teleflex Medical Sdn. Bhd.
Yuvaanesswary Nallappan
Regulatory Affairs Manager
Lot PT 2577,
Jalan Perusahaan 4
Kamunting, Perak 34000
MALAYSIA

Re: K252537
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: August 12, 2025
Received: December 19, 2025

Dear Yuvaanesswary Nallappan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252537

Please provide the device trade name(s).

Rusch SoftSimplastic Foley Catheters

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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

Teleflex Medical Sdn. Bhd.
Lot PT 2577, Jalan Perusahaan 4,
34600 Kamunting,
Perak, Malaysia.

B. Contact Person

Yuvaanesswary Nallappan
Regulatory Affairs Manager

C. Date Prepared

January 19, 2026

D. Device Name

Trade Name:	Rüsch SoftSimplastic Foley Catheters
Common Name:	Catheter, Retention Type, Balloon
Product Code:	EZL
Regulation Number:	CFR 876.5130
Classification:	II
Classification Panel:	Gastroenterology/Urology

E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device, Teleflex Medical Rüsch SoftSimplastic Foley Catheter, K212077.

F. Device Description

The RÜSCH SoftSimplastic balloon 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 in ml and shaft size in French gauge (Fr.), Charrière (Ch.) or millimeters (mm) are indicated on the funnel of each individual catheter. They have a radiopaque contrast stripe along the shaft and are supplied sterile.
The following tip types are available: Couvelaire and Coudé/Mercier. Sizes range from 14 to 24 Ch./Fr. The catheters have a length of approximately 42 cm.
The RÜSCH SoftSimplastic balloon catheters are made of PVC uncoated. These catheters are only for short term usage. Maximum duration of use: Up to 30 days.

G. 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.

H. Contraindications

- Latex allergy
- Insurmountable urethral obstructions
- Urethral injuries
- Urethral inflammation
- False passage

I. Substantial Equivalence

The subject Rüsch SoftSimplastic Foley Catheter is substantially equivalent to the predicate device with respect to intended use, technology and construction. **Table 1** summarizes the comparison between the subject and predicate device.

Table 1: Comparison of Predicate Device vs. Subject Device

Features	Teleflex Medical Rüsch SoftSimplastic Foley Catheter (Predicate Device - K212077)	Teleflex Medical Rüsch SoftSimplastic Foley Catheter (Subject Device)	Similarities and Differences
Classification Name	Catheter, Retention Type, Balloon	Catheter, Retention Type, Balloon	Same
Regulation Number	876.5130	876.5130	Same
FDA Product Code	EZL	EZL	Same
Class	II	II	Same
Indications for Use	2 Way SoftSimplastic Catheters: Indicated where routine drainage of the bladder is required either postoperatively or for patients with conditions requiring urine drainage. 3 Way SoftSimplastic Catheters: Indicated where routine drainage of the bladder is required either postoperatively, for patients with conditions requiring urine drainage and for patients requiring bladder irrigation.	2 Way SoftSimplastic Catheters: Indicated where routine drainage of the bladder is required either postoperatively or for patients with conditions requiring urine drainage. 3 Way SoftSimplastic Catheters: Indicated where routine drainage of the bladder is required either postoperatively, for patients with conditions requiring urine drainage and for patients requiring bladder irrigation.	Same
Contraindications	• Latex allergy • Insurmountable urethral obstructions • Urethral injuries • Urethral inflammation • False passage	• Latex allergy • Insurmountable urethral obstructions • Urethral injuries • Urethral inflammation • False passage	Same
Single Use	Yes	Yes	Same
Population	Adult, Male and Female	Adult, Male and Female	Same
Size Range	Male/Female 14-24 Fr.	Male/Female 14-24 Fr.	Same

Features	Teleflex Medical Rüsch SoftSimplastic Foley Catheter (Predicate Device - K212077)	Teleflex Medical Rüsch SoftSimplastic Foley Catheter (Subject Device)	Similarities and Differences
Indwelling Time	Maximum indwell time less than 30 days	Maximum indwell time less than 30 days	Same
Single Use	Yes	Yes	Same
Lumens	2-way and 3-way	2-way and 3-way	Same
Nominal Balloon Inflation Volume	30ml and 75ml	30ml and 75ml	Same
Shaft Material	PVC	PVC	Same
Coated or uncoated	Uncoated	Uncoated	Same
Eyelets	Yes	Yes	Same
Primary Packaging	Paper and film peel back	Paper and film peel back	Same
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Same
MR Condition	Safety in MRI Not Evaluated	MR Conditional	Different

J. Comparison of Technological Characteristics with the Predicate Device

The Rüsch SoftSimplastic Foley Catheters have the same fundamental technological characteristics as the predicate device, Teleflex Medical Rüsch SoftSimplastic Foley Catheter (K212077).

Both subject and predicate devices are sterile, single-use, short-term indwelling balloon catheters designed for transurethral bladder drainage.

Both subject and predicate devices are based on the same technological principles and design features, including:

- A flexible PVC shaft available in 2-way and 3-way lumen configurations.
- A distal balloon made of latex to retain the catheter within the bladder.
- A proximal funnel and inflation valve for urine drainage and balloon inflation.
- A radiopaque stripe along the shaft for X-ray visibility.

- Ethylene oxide sterilization and single-use packaging.
- Intended for short-term use (up to 30 days) in adult male and female patients.

The following minor differences exist between the subject and predicate devices:

- The subject device has undergone magnetic resonance (MR) safety and compatibility testing and is now labeled as MR Conditional in accordance with ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119, and ASTM F2503.
- The predicate device did not include MR labeling and was not previously evaluated for MR safety.

The devices otherwise share identical materials, configuration, functional principles, and performance characteristics.

K. Summary of Non-Clinical Testing

MR Safety and Compatibility testing was performed per the standards listed below.

- ASTM F2052-21 "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"2
- ASTM F2213-17 "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"
- ASTM F2182-19e2 "Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during Magnetic Resonance Imaging"
- ASTM F2119-07 (2013) "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"
- ASTM F2503-23 "Standard Practice for Marking Devices and Other items for Safety in the Magnetic Resonance Environment"

The device was determined to be MR Conditional when used under the specific conditions defined in the device labeling.

L. Conclusion

The **Rüsch SoftSimplastic Foley Catheters** have the same intended use and technological characteristics as the predicate device. Test results demonstrate that the subject devices meet their intended use and performs as well as the legally marketed predicate device. The subject device is substantially equivalent to the predicate device.