August 5, 2026

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

Re: K262056
Trade/Device Name: Rusch Latex Gold Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: June 18, 2026
Received: June 18, 2026

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANDREW M. FALES -S

for 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.	K262056

Please provide the device trade name(s).

Rusch Latex Gold Foley Catheter

Please provide your Indications for Use below.

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

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

Catheters are indicated for use in male and female adults and pediatric patients with the following pediatric subgroups:
Children (2 years old to less than 12 years old),
Adolescents (12 years old to less than 18 years old), and
Transitional Adolescents (18 years old to less than 22 years old but treated like an adult).

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

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

Teleflex Medical Sdn. Bhd.
Lot No. PT577, Jalan Perusahaan 4,
Kamunting Industrial Estate,
34600 Kamunting, Perak, Malaysia.
Tel: +6058711622

B. Contact Person

Yuvaanesswary Nallappan
Regulatory Affairs Manager
Email – Yuvaanesswary.Nallappan@teleflex.com

C. Date Prepared

August 5, 2026

D. Device Name

Trade Name:	Rusch Latex Gold Foley Catheter
Common Name:	Catheter, Retention Type, Balloon
Product Code:	EZL
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 Latex Gold Foley Catheter, K232469. The predicate device has not been subjected to design-related recall.

F. Device Description

The Rüsch Latex Gold Foley Catheter family includes the Gold and Gold Pediatric Foley catheters are made of natural rubber latex with different nominal balloon inflation volumes (range from 3 ml to 30 ml), with cylindrical tip type and in a size range of 8 to 26 Ch./Fr. The catheters have a length of approximately 40 cm except for Gold Pediatric have a length of 30 cm. Balloon inflation volumes in ml, shaft size in French gauge (Fr.) or Charrière (Ch.) and Outer Diameter (OD) in mm are indicated on the funnel of each individual catheter. These catheters are silicone treated and supplied

sterile. Pediatric catheters (sizes 8 Ch. to 10 Ch.) include a stylet to facilitate insertion. The Latex Gold Foley Catheter maximum use/indwelling period is less than 30 days.

G. Indications for Use

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

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

Catheters are indicated for use in male and female adults and pediatric patients with the following pediatric subgroups:
Children (2 years old to less than 12 years old),
Adolescents (12 years old to less than 18 years old), and
Transitional Adolescents (18 years old to less than 22 years old but treated like an adult).

H. Contraindications

- Latex allergy
- Insurmountable urethral obstruction
- Urethral injuries
- Urethral inflammation
- False passage
- Acute orchitis
- Acute prostatitis
- Acute epididymitis

I. Substantial Equivalence

The subject Rusch Latex Gold Foley Catheter is substantially equivalent to the predicate device with respect to intended use, technology and construction. **Table 1** summarizes the similarities and differences between the subject and predicate device.

Table 1: Comparison of Predicate Device vs. Subject Device

Features	Teleflex Medical Sdn. Bhd. Rusch Latex Gold Foley Catheter (K232469 - **Predicate Device**)	Teleflex Medical Rusch Latex Gold 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 Procode	EZL	EZL	Same
Class	II	II	Same
Indications for Use	2 Way Latex Foley Catheters: Indicated where routine drainage of the bladder is required either postoperatively or for patients with conditions requiring urine drainage. 3 Way Latex Foley Catheters: Indicated where routine drainage of the bladder is required either postoperatively or for patients with conditions requiring urine drainage and for patients requiring bladder irrigation.	2 Way Latex Foley Catheters: Indicated where routine drainage of the bladder is required either postoperatively or for patients with conditions requiring urine drainage. 3 Way Latex Foley Catheters: Indicated where routine drainage of the bladder is required either postoperatively or for patients with conditions requiring urine drainage and for patients requiring bladder irrigation.	Same
Contraindications	- Latex allergy - Insurmountable urethral obstruction - Urethral injuries - Urethral inflammation - False passage - Acute orchitis - Acute prostatitis - Acute epididymitis	- Latex allergy - Insurmountable urethral obstruction - Urethral injuries - Urethral inflammation - False passage - Acute orchitis - Acute prostatitis - Acute epididymitis	Same

Features	Teleflex Medical Sdn. Bhd. Rusch Latex Gold Foley Catheter (K232469 - **Predicate Device**)	Teleflex Medical Rusch Latex Gold Foley Catheter (**Subject Device**)	**Similarities and Differences**
Single Use	Yes	Yes	Same
Population	Adult and Pediatric, Male and Female	Adult and Pediatric, Male and Female	Same
Size Range	Pediatric 8-10 Fr. Male/Female 12-26 Fr.	Pediatric 8-10 Fr. Male/Female 12-26 Fr.	Same
Indwelling Time	Maximum indwell time less than 30 days	Maximum indwell time less than 30 days	Same
Lumens	2-way and 3-way	2-way and 3-way	Same
Nominal Balloon Inflation Volume	3cc, 5cc, 30cc	3cc, 5cc, 30cc	Same
Shaft	Tubular	Tubular	Same
Material	Natural latex (Vulcanized)	Natural latex (Pre-vulcanized)	Both devices are made from natural latex. Subject device uses pre-vulcanized latex, while predicate device uses vulcanized latex.
Surface Finish (Coating)	Silicone or Polytetrafluoroethylene (PTFE)	Silicone	Same. Subject device is coated with silicone only
Eyelets	Yes	Yes	Same
Primary Packaging	Paper & film	Paper & film	Same
Sterile	Yes	Yes	Same
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Same
Magnetic Resonance (MR) environment	MR conditional	MR conditional	Same

J. Comparison to the Predicate

The subject device, Rüsch Latex Gold Foley Catheters, is currently cleared under K232469 and manufactured by Teleflex Medical Sdn. Bhd. The device is being transferred to Teleflex Medical IDA Business and Technology Park, Athlone, Ireland, as the Legal Manufacturer, with manufacturing to be performed by Teleflex Medical Private Ltd., Puducherry, India.

The subject device has the same intended use, indications for use, and fundamental technological characteristics as the predicate device, Rüsch Gold Foley Catheter (K232469). Both devices are sterile, single-use, short-term indwelling balloon catheters made from natural latex and intended for transurethral bladder drainage in pediatric and adult patients for up to 30 days. Both devices incorporate the same key design features, including 2-way and 3-way lumen configurations, a retention balloon, a proximal funnel and inflation valve, and gamma sterilization.

Following the manufacturing transfer, the subject device will be manufactured at the Puducherry facility using its established manufacturing processes, materials, inspection procedures, and sterilization method. The primary difference between the subject device and the predicate device is the use of pre-vulcanized latex instead of vulcanized latex. The pre-vulcanized latex formulation was not previously reviewed under the K232469 clearance. However, the subject and predicate devices are both manufactured of natural latex.

K. Summary of Non-Clinical Testing

- Biocompatibility tests was conducted per ISO 10993-1– Biological Evaluation of Medical Devices -Part 1: Evaluation and testing within a risk management process:
    - Cytotoxicity
    - Sensitization
    - Intracutaneous Irritation
    - Material Mediated Pyrogenicity
    - Acute Systemic Toxicity
    - Subacute Toxicity
    - Implantation Test
    - Genotoxicity

- Sterilization validation was conducted per the following FDA-recognized standards:
    - ISO 11137-1 – Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
    - ISO 11137-2– Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose.

- ISO 11737-2 Sterilization of medical devices. Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

- Transportation simulation, package integrity testing, and shelf-life evaluation were performed to demonstrate that the subject device packaging can withstand the rigors of shipping and distribution while maintaining the sterile barrier system (SBS) throughout transportation and the claimed shelf life. Testing was conducted in accordance with EN ISO 11607-1, ASTM F2096, ASTM F1886/F88M, ASTM F88/F88M, ASTM D4169, and ASTM D4322.

- Performance/Functional testing was conducted per ASTM F623: Standard Performance Specification for Foley Catheter and ISO 20696: Sterile Urethral Catheters for Single Use.

- MR safety and compatibility testing was performed per ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119 and ASTM F2503. The device was determined to be MR Conditional when used under the specific conditions defined in the device labeling.

L. Conclusion

The **Rusch Latex Gold Foley Catheters** have the same intended use and technological characteristics as the predicate. Although the subject device uses a different latex formulation than the predicate device, both the subject and predicate are made from natural rubber latex. Test results demonstrate that the subject devices meet their intended use and perform as well as the legally marketed predicate device. It is for these reasons that the subject device can be found to be substantially equivalent.