August 1, 2024

Teleflex Medical, Inc.
Angela Bouse
Senior Manager, Regulatory Affairs - Product Management
3015 Carrington Mill Blvd, Suite 600 North
Morrisville, North Carolina 27560

Re: K232469
Trade/Device Name: Rüsch Latex Gold Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: August 14, 2003
Received: July 18, 2024

Dear Angela Bouse:

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.

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,

Sharon M. Andrews -S

for Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
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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)*
K232469

Device Name
Rüsch Latex Gold Foley Catheter

Indications for Use *(Describe)*

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.

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.

TRADITIONAL 510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant & Official Correspondent

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Date Prepared: July 31, 2024

2. DEVICE NAME

Trade Name of the Device	Rüsch Latex Gold Foley Catheter
Common Name:	Foley Catheter
Classification Name:	Urological catheter and accessories
Classification Regulation:	21 CFR 876.5130
Device Class:	II
Product Code:	EZL (Catheter, Retention Type, Balloon)
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE IDENTIFICATION

K173340, YiKang Latex Foley Catheter

The predicate device was never subjected to a design related recall.

4. DEVICE DESCRIPTION:

The Rüsch Latex Gold Foley Catheter is available as 2 Way catheter, with a proximal funnel, non-return inflation valve and bladder fixation balloon, and 3 Way catheter which includes an additional irrigation channel with proximal funnel. The catheter is manufactured of natural latex, provided sterile, single use, and disposable. The inflation valve is designed for use with Luer and Luer lock syringe tips. Balloon inflation volumes in millimeters, as well as shaft size in French gauge (Fr.), Charrière (Ch.), or millimeters (mm), are indicated on the funnel of each individual catheter. The catheters are siliconized, or surface finished with Polytetrafluoroethylene (PTFE). The Gold Foley Catheter maximum use/indwelling period is less than 30 days. The device has different models of catheters namely **PURE GOLD, Gold Pediatric, Gold, and the Gold Haematuria**.

PURE GOLD

The Coudè Foley Catheter PURE GOLD is designed with a Coudè tip and one eye. Catheter dimensions range from 12 Fr. to 24 Fr. and have a range of 4.00 mm to 8.67 mm in Outer Diameter. The catheters have an overall length of 402-422 mm. The nominal balloon inflation volume for this model is 5 or 30 cm^3.

Gold Pediatric

The Gold Pediatric Foley Catheter is designed with a cylindrical tip and two opposing eyes. The 8 Fr. and 10 Fr. catheter have a range of 2.67 mm to 3.33 mm in Outer Diameter (OD). The catheters have an overall length of 287-307 mm. The 8 Fr. and 10 Fr. catheter include a pre-loaded stylet (Nylon- 0.65 mm Clear) to facilitate insertion. The nominal balloon inflation volume for this model is 3 cm^3.

Gold

The Gold 2 Way Foley Catheter is designed with a cylindrical tip and two opposing eyes. Catheter size ranges from 12 Fr. to 24 Fr. and have a range of 4.00 mm to 10.00 mm in Outer Diameter (OD). The catheter has a length of 397-417 mm.
The Gold 3 Way Foley Catheter is designed with a cylindrical tip and two vertically oriented eyes. Catheter size ranges from 16 Fr. to 26 Fr. for the 3-way shaft. There is a range of 6.00 mm to 7.33 mm in the catheter Outer Diameter (OD). The catheter has a length of 397-417 mm.
The nominal balloon inflation volume for this model is 5 or 30 cm^3.

Gold Haematuria

The Gold 3 Way Haematuria catheter is designed with a cylindrical tip and two vertically oriented eyes. Catheter size ranges from 18 Fr. to 24 Fr. and has a 3-way shaft. There is a range of 6.00 mm to 8.00 mm in the catheter Outer Diameter (OD). The catheter has a length of 397-417 mm. A portion of the shaft includes a nylon winding enabling shaft to be rigid. The nominal balloon inflation volume for this model is 30 cm^3.

5. 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison Element	**Subject Device:** Rüsch Latex Gold Foley Catheter	**Predicate Device:** YiKang Latex Foley Catheter
510(k) Number	K232469	K173340
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.	The YiKang Foley Catheter is intended to be placed in the bladder, through the urethra, to drain urine and other fluids from the urinary bladder
Prescription use	Yes	Yes
Intended Population	Adult and Pediatric, Male and Female	Adult and Pediatric, Male and Female
Device usage	Single use sterile	Single use sterile
Size Range	Pediatric: 8-10 Fr. Male/Female:12-26 Fr.	Pediatric: 6-10 Fr. Male/Female: 12-30 Fr.
Overall catheter length	PURE GOLD: 402-422 mm Gold Pediatric: 287-307 mm Gold & Gold Haematuria: 397-417 mm	Pediatrics: 260-280 mm 2-Way Male: 390-410 mm 2-Way Female: 255-270 mm 3-Way Standard: 390-410 mm
Effective length	PURE GOLD: 355 (+20, -15) mm Gold Pediatric 245 (+15, -20) mm Gold 360 (+10, -25) mm Gold Haematuria 345 (+25, -10) mm	Pediatrics 190-200 mm 2-Way Male: 280-300 mm 2-Way Female: 150-165 mm 3-Way Standard: 280-300 mm

Indwelling time	Maximum indwell time less than 30 days	Maximum indwell time of less than 30 days
Lumens	2-way and 3-way	2-way and 3-way
Nominal Balloon Inflation Volume	3 cm^3, 5 cm^3, 30 cm^3	3 cm^3, 5 cm^3, 30 cm^3
Shaft	Tubular	Tubular
Material	Natural latex	Natural latex
Surface Finish (Coating)	Silicone	Silicone or PTFE
Eyelets	Yes	Yes
Primary Packaging	Paper and film peel back	Paper and film peel back
Sterile	Yes	Yes
Sterilization Method	Ethylene Oxide, ISO 11135	Gamma Irradiation, ISO 11137-2
Stylet	Yes, in Gold pediatric	Not included
Tip shape	Coude and cylindrical	Cylindrical

As evidenced by the above table, both the subject and the predicate devices have similar intended use, but the subject and predicate devices have different technological characteristics. The differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

7. SUMMARY OF NONCLINICAL TESTING:

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility was conducted per ISO 10993-1:2018– Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process and Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process", issued September 2023. The following tests were conducted in the biocompatibility assessment of the device:
  - Cytotoxicity per ISO 10993-5:2009.
  - Sensitization per ISO 10993-10:2021.
  - Irritation per ISO 10993-23:2021.
  - Acute Systemic Toxicity per ISO 10993-11:2017.
  - Subacute Systemic Toxicity per ISO 10993-11:2017.
  - Material Mediated Pyrogenicity per ISO 10993-11:2017.
  - Implantation per ISO 10993-6:2016.

  The results of biocompatibility testing demonstrate that the subject device is biocompatible.

- Sterilization validation was conducted per the following FDA-recognized standards:
  - ISO 11137-1:2006 (R)2015 – Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
  - ISO 11137-1:2013 – Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose.

- Accelerated aging was performed in conformance with ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices to support the shelf life of the device. The results of accelerated aging testing demonstrate that the subject device maintains its function performance and that its packaging maintains the sterility of the device over the duration of its shelf life via bench testing and transportation simulation and package integrity testing, respectively.

- Performance/Functional testing was conducted per ASTM 623-19 Standard Performance Specification for Foley Catheter. The subject device met the acceptance criteria outlined in the standard.

8. CONCLUSIONS

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate device.