November 12, 2024

Coloplast Corp.
Jennifer Tvrdik
Senior Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, Minnesota 55411

Re: K242173
Trade/Device Name: Retrace Ureteral Access Sheath (ASXL10, ASXL12, ACXL10, ACXL12, AXXL10, AXXL12, ALXL10, ALXL12)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: July 24, 2024
Received: October 7, 2024

Dear Jennifer Tvrdik:

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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242173

Device Name

Retrace Ureteral Access Sheath (ASXL10, ASXL12, ACXL10, ACXL12, AXXL10, AXXL12, ALXL10, ALXL12)

Indications for Use *(Describe)*

To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

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.

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"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."

2.03 510(k) SUMMARY

I. SUBMITTER

510(K) Owner's Name: Coloplast A/S

Legal Manufacturer Address: Holtedam 1
3050 Humlebaek, Denmark

Phone/Fax/Email: Phone: (612) 998-4517
Email: usjtvr@coloplast.com

Name of Contact Person: Jennifer Tvrdik
Sr. Regulatory Specialist

Address/Contact: 1601 West River Road North
Minneapolis, MN 55411

Date Prepared: July 12, 2024

II. DEVICE

Trade or Proprietary Name: ReTrace® Ureteral Access Sheath

Common or Usual Name: Endoscopic Access Overtube, Gastroenterology-Urology

Classification Name: Endoscope Access Overtube
(21 CFR section 876.1500)
Product Code: FED
Device Class: 2

Classification Panel: Gastroenterology-Urology

III. PREDICATE DEVICE

Primary Predicate:	ReTrace Ureteral Access Sheath
510(k) Holder:	Coloplast A/S
510(k) Number:	K181811

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ReTrace Ureteral Access Sheath is a sterile, single use device that is inserted over a guidewire into the upper or lower urinary tract of patients requiring ureteroscopic procedure sin a hospital environment. The ReTrace Ureteral Access Sheath consists of:

- Reinforced tube/sheath
- Introducer/dilator
- Connector
- Clip

The reinforced polymeric introducer sheath includes a hydrophilic coating on the exterior and a lubricious inner surface. The sheath is reinforced to provide kink resistance. The distal tip of the sheath is fitted with a radiopaque ring. A white connector is fitted on the proximal end of the sheath and an orange connector is on the proximal end of the introducer to allow the two components to be attached.

The dilator is fitted with a Luer connector on the proximal end and has a hydrophilic coating on the distal end. A guidewire entry and exit eye and exit holes for fluid delivery are located at the distal end of the introducer. The dilator protrudes out the distal end and allows for a gradual enlargement of the passage if needed and improves trackability along the guidewire. Once in the desired location, the dilator is removed to establish a hollow conduit for insertion of endoscopes and other instruments into and out of the urinary tract.

The ReTrace Ureteral Access Sheaths are available in two diameters 10/12 Fr and 12/14 Fr. Lengths range between 28 and 55 cm.

This submission is for modifications to device materials, labeling, packaging, and connector design.

V. INDICATIONS FOR USE

To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified ReTrace Ureteral Access Sheath is substantially equivalent in performance, indication, design, and materials to the previously cleared, ReTrace Ureteral Access Sheath (K181811) as shown in **Table 1**.

Table 1: Comparison of Technological Characteristics

Device Feature/ Component	ReTrace Ureteral Access Sheath (Subject Device)	ReTrace Ureteral Access Sheath K181811 (Primary Predicate)
Manufacturer	Coloplast A/S	Coloplast A/S
510 (k) number	510(k) Pending	K181811
Regulation name	Endoscopic Access Overtube	Endoscopic Access Overtube
Regulation number	21 CFR 876.1500	21 CFR 876.1500
Classification product code	FED	FED
Classification	II	II
Prescription device	Yes	Yes
Intended Use	To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.	Used to establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.
Duration of Use	During procedure <24 hrs	During procedure <24 hrs
Target Patient Population	Patients requiring ureteroscopic procedures.	Patients requiring ureteroscopic procedures.
Anatomical sites	Upper and lower urinary tract	Upper and lower urinary tract
Where used (hospital, home, ambulance, etc.)	Hospital	Hospital
Components	The ReTrace UAS is comprised of four components: • Reinforced tube/sheath • Introducer/dilator • Connector • Clip	The ReTrace UAS is comprised of four components: • Reinforced tube/sheath • Introducer/dilator • Connector • Clip
Sizes	10 FR ID / 12 FR OD 12 FR ID / 14 FR OD	10 FR ID / 12 FR OD 12 FR ID / 14 FR OD
Length	28 cm through 55 cm	28 cm through 55 cm
Performance	Testing of dimensions, device integrity, device functionality, simulated use, guidewire pullout force, kink resistance, injection testing, and shelf-life testing to support 5 years	Testing of dimensions, device integrity, device functionality, simulated use, guidewire pullout force, kink resistance, injection testing, and shelf-life testing to support 5 years
Insertion Technique	Insertion over a guidewire	Insertion over a guidewire
Device Materials	PEBA, PTFE, stainless steel, PVC, polycarbonate, Nitinol	PEBA, PTFE, stainless steel, PVC, polycarbonate, Nitinol
Coating	Hydrophilic coating	Hydrophilic coating
Single use	Yes	Yes
Biocompatibility per ISO 10993	Meets Standard	Meets Standard
Sterilization method	Ethylene Oxide	Ethylene Oxide

Device Feature/ Component	ReTrace Ureteral Access Sheath (Subject Device)	ReTrace Ureteral Access Sheath K181811 (Primary Predicate)
Sterility Assurance Level	10^{-6}	10^{-6}
Shelf Life	5 years	5 years

VII. PERFORMANCE DATA

The following testing data was provided in support of the substantial equivalence determination and changes to the product line.

Biocompatibility Testing

Biocompatibility testing was conducted based upon ISO 10993-1 (2018): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA Guidance for Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff – September 2020.

Mechanical Testing

Mechanical testing was completed in support of the substantial equivalence determination and changes to the product line.

- Visual Inspection
- Dimensional Inspection
- Viscous fluid test
- Simulated use test
- Compatibility with accessories
- Compatibility with Solutions
- Peelability test
- Tensile strength on introducer
- Tensile strength between introducer and luer
- Tensile strength between connector and sheath
- Folding resistance on sheath
- Radiopacity test on introducer
- Friction test on sheath
- Friction test on introducer tip
- No perforation test
- Tip flexibility
- Nitinol tube compression / position
- Shelf life testing to support 5 years

Sterilization

The ReTrace Ureteral Sheaths are sterilized using ethylene oxide in a validated cycle demonstrating a microbial assurance level of 10^{-6}.

Packaging and Distribution

Packaging testing included dye penetration testing, peel strength, peelability and visual inspection including through five year simulated accelerated aging.

No animal studies or clinical testing were provided to support substantial equivalence between the subject and predicate device.

VIII. CONCLUSIONS

The modifications to the ReTrace Ureteral Access Sheath have been demonstrated to be substantially equivalent to the primary predicate, ReTrace Ureteral Access Sheath, based on the non-clinical data provided. The test results demonstrate that the design and labeling changes do not raise new questions of safety or effectiveness and are substantially similar to the predicate.