December 21, 2017

Coloplast Corp.
Cori L. Ragan
Regulatory Affairs Manager
1601 West River Road North
Minneapolis, MN 55411

Re: K171043
Trade/Device Name: Ureteric catheters, Flush Ureteric catheters, Floppy Tip Hydro-Coated Ureteric Catheters
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EYB
Dated: November 22, 2017
Received: November 28, 2017

Dear Cori L. Ragan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K171043

Device Name
Ureteric catheters / Flush Ureteric catheters / Floppy Tip Hydro-Coated Ureteric Catheters

Indications for Use *(Describe)*

Ureteric catheters are intended for endourological procedures, to restore or maintain drainage of the upper urinary tract and to inject contrast medium or saline.

Duration of use: Ureteric catheters are intended for temporary use during surgical procedure.

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

## I. Submitter

**510(k) Owner:** Coloplast A/S
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**Contact Person:** Cori Ragan
Regulatory Affairs Manager
1601 West River Road
Minneapolis, MN 55411
Phone: 612.597.5106
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**Date Prepared:** 22 November 2017

## II. Device

**Trade or Proprietary Name:** Ureteric Catheters
Flush Ureteric Catheters
Floppy Tip Hydro-Coated Ureteric Catheters

**Common or Usual Name:** Ureteric Catheters

**Classification name:** Urological catheter and accessories
(21CFR section 876.5130)

**Regulatory Class:** II

**Product Code:** EYB

## III. Predicate Device

| | |
|---|---|
| Trade Name: | Pigtail Ureteral Catheter set (K962004) |
| Common / Usual Name: | Catheter, Ureteral, Gastro-Urology |
| Classification Name: | Urological catheter and accessories (21CFR section 876.5130) |
| Reference Device: | Porges Ureteral Catheters (K021856) |
| Common / Usual Name: | Ureteral Catheters |
| Classification Name: | Urological catheter and accessories (21CFR section 876.5130) |

## IV. Device Description

Ureteric catheters are ethylene oxide sterilized, single use devices intended to restore or maintain drainage of the upper urinary tract and to flush or inject contrast medium or saline during an endoscopic procedure. All ureteric catheters include a connector nut with a Luer fitting. The connector nut is inserted into the proximal end of the catheter allowing

the Luer fitting to connect to collecting or injection devices. Ureteric catheters are open at the distal end (farthest away from the surgeon) to allow use over a guidewire.

Flush Ureteric Catheters and Ureteric Catheters come in three different tip configurations (straight, open coudé with side eyes, open coudé without side eyes). A stylet in included with the catheters to aid during the catheter insertion. The Flush Ureteric Catheters and Ureteric Catheters are supplied in a 74 cm length and diameters range from 3 Fr. to 8 Fr. The Floppy Tip Hydro-coated Ureteric catheters are 70 cm long and have 5,6, and 7 Fr. diameters.

The Flush Ureteric Catheters and Ureteric Catheters are made from polyether block amide materials. The Floppy Tip Hydro-coated Ureteric catheters are made from polyvinyl chloride (PVC), have a hydrophilic coating over the distal tip (farthest away from the surgeon), and a soft tip which allows for easier insertion and advancement of the catheter. The materials have a radiopaque filler to allow for fluoroscopic visibility.

## V. Indications for Use / Intended Use

Ureteric catheters are intended for endourological procedures, to restore or maintain drainage of the upper urinary tract and to inject contrast medium or saline.

Duration of use: Ureteric catheters are intended for temporary use during surgical procedure.

## VI. Comparison of Technological Characteristics with the Predicate Device

The Ureteric Catheters, Flush Ureteric Catheters, and Floppy Tip Hydro-Coated Ureteric Catheters are similar to the predicate and reference device in that the following parameters:

- All devices are hollow, polymeric tubes for urological drainage
- The devices are supplied sterile and intended for single use.
- The predicate device and Floppy Tip Hydro-Coated Ureteric Catheter both have a hydrophilic coating to minimize friction.
- The reference device and the Ureteric catheters included devices which are uncoated and made from the same polyether block amide materials.
- The predicate device is supplied in 5.0 – 8.0 Fr diameters and 70 cm lengths and the reference device is available in 3 .0 – 10.0 Fr diameters and 70 cm lengths. These available configurations are essentially equivalent to the subject devices.
- The subject, predicate, and reference devices have side eyes (sideports) on some models.
- The subject and reference devices both include stylets for ease of insertion.
- The subject and reference devices both include a connector nut with a Luer connector to allow for connection to a drainage device or syringe.

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

- The predicate device is supplied with a round, pigtail end while the subject devices are supplied with straight and coudé tips.

## VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

### Biocompatibility Testing

The biocompatibility evaluation for the Ureteric Catheters device was conducted in accordance with ISO 10993-1 and FDA guidance document for Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices part I: Evaluation and Testing within a risk management system". The Ureteric Catheters, Flush Ureteric Catheters, and Floppy Tip Hydro-coated Ureteric catheters are categorized as surface contacting devices in contact with mucous membrane for a limited (<24 hours) duration. The time of contact is assessed based on the total accumulated use time, when the device is used as intended.

The battery of biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity (Floppy Tip Hydro-Coated Ureteric Catheter only)
- Sub-chronic toxicity (Subacute toxicity) (Floppy Tip Hydro-Coated Ureteric Catheter only)
- Implantation (Floppy Tip Hydro-Coated Ureteric Catheter only)

### Performance Testing

Performance testing was conducted with samples at T=0 and after 5 years accelerated aging. The battery of performance testing included the following tests:

- Visual
- Compatibility
- Dimensional
- Viscous Fluid Test / Injection of contrast liquid
- Flow Rate
- Tensile
- Friction Strength Test (distal tip)
- Radiopacity

The results of the performance testing demonstrate that the Ureteric Catheters, Flush Ureteric Catheters, and Floppy Tip Hydro-coated Ureteric catheters are safe and effective for their intended use throughout the product shelf life.

## VIII. Conclusion

Substantial equivalence is supported by bench testing comparing the design, materials, intended use, technological characteristics, biocompatibility, and performance of the Ureteric Catheters, Flush Ureteric Catheters, and Floppy Tip Hydro-Coated Ureteric Catheters to the predicate and reference devices. Based on the entire comparison, the Ureteric Catheters, Flush Ureteric Catheters, and Floppy Tip Hydro-Coated Ureteric Catheters are substantially equivalent to products currently on the market.