August 2, 2023

Coloplast Corporation
Preeti Jain
Head of Regulatory Affairs
1601 West River Road North
Minneapolis, MN 55411

Re: K223821
Trade/Device Name: Self-Cath Closed System
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: FCM
Dated: July 7, 2023
Received: July 7, 2023

Dear Preeti Jain:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,
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Office of Product Evaluation and Quality
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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)*
K223821

Device Name
Self-Cath Closed System

Indications for Use *(Describe)*
Self-Cath Closed System is intended for use in male and female adult patients requiring bladder drainage as determined by their physician. The device is indicated for individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

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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## TRADITIONAL 510(K) SUMMARY

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|---|---|
| **Submitted by:** | Coloplast A/S<br>Holtedam1<br>3050 Humlebaek<br>Denmark |
| **Contact Person :** | Preeti Jain<br>Head of Regulatory Affairs, North America<br>Coloplast<br>1601 West River Road North<br>Minneapolis MN 55411<br>Phone: +1 (612)-413-5614<br>Email: uspj@coloplast.com |
| **Date of Summary:** | July 21, 2023 |
| **Trade or Proprietary Name:** | Self-Cath Closed System |
| **Item Numbers:** | 50270/1108, 50271/ C1110, 50272/1112, 50273/1114, 50274/1116, 50277/2114, 50281/2214, 50285/2614, 50286/2814, 50287/2816 |
| **Common or Usual Name:** | Intermittent Catheter, Urethral |
| **Regulation Name:** | Urological Catheter and Accessories |
| **Regulation Number** | 21 CFR 876.5130 |
| **Device Class:** | Class II |
| **Product Code** | FCM |
| **Review Panel:** | Gastroenterology/Urology |
| **Predicate Device:** | Self-Cath & Self-Cath Plus K221401<br>The predicate device has not been subject of a design related recall. |
| **Reference Device:** | Self-Cath Closed System, K070939<br>The reference device has not been subject of a design related recall. |

**Device Description:**

The **Self-Cath Closed System** is a disposable single-use, catheter designed for intermittent catheterization integrated with a urine collection bag. The device is sterilized with ethylene oxide (EO) sterilization. The catheter is made with PVC with DEHT as a plasticizer. The Self-Cath catheter used in the system is identical to the catheter recently cleared in K221401.The catheter is provided with a gel lubricant that is placed inside a urine bag, which is closed off with a protection cap (introducer tip cap). During use, the protection cap is removed, and the catheter is pushed out of the urine bag through the introducer tube and tip. The drainage end of the catheter is inside the bag allowing urine to be drained directly into the bag. The urine bag has a tear off section to open the urine bag for emptying.

The Self-Cath Closed System includes gloves, swab sticks, a wipe, and a drape in addition to the components above.

**Indications for Use:**

**Self-Cath Closed System** is intended for use in male and female adult patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

**Technological Characteristics:**

The subject devices have the same intended use, indications for use, principles of operation, technological characteristics, and performance specifications as the predicate device.

| | **Subject device** | **Predicate device** | **Reference device** |
|---|---|---|---|
| **Product** | **Self-Cath Closed System** | **Self-Cath and Self-Cath Plus** | **Self-Cath Closed System** |
| 510(k) Number | K223821 | K221401 | K070939 |
| Regulation Name | Urological catheter and accessories | Urological catheter and accessories | Same |
| Regulation Number | 21 CFR876.5130 | 21 CFR 876.5130 | Same |
| Product Code | FCM | EZD | Same |
| Classification | II | Same | Same |
| Prescription Device | Yes | Same | Same |

| | | | |
|---|---|---|---|
| Intended Use | The product is intended for intermittent catheterization through the urethra | Same | Same |
| Indications for Use | Self-Cath Closed System is intended for use in male and female adult patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode. | Self-Cath is intended for use in male, female, and pediatric patients (neonates, infants, children, adolescents, and transitional adolescents) requiring bladder drainage as determined by their physician. The devices are indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode. | Self-Cath CS Closed System is intended for use in male or female patients needing bladder drainage as determined by their physician. More specifically it is intended for use where drainage of the bladder into a suitable receptable such as a commode or bedpan is not feasible or practical. The device can be used by either the patient, once appropriate training has taken place, or by a trained health care professional. |
| Condition of Use | Intermittent and Single-Use | Same | Same |
| Sterility | $10^{-6}$ | Same | Same |
| Sterilization Method | Ethylene Oxide (EO), Half cycle, Over-kill | Same | Same |
| Shelf Life | 3 years | Same | Same |
| Variants | Male, Female | Male, Female and Pediatrics | Same |
| Catheter Materials | PVC with DEHT (Shore A 70 and 80) | PVC with DEHT (Shore A 70, 80 and 85) | PVC with DEHP (Shore A 70 and 80) |
| Hydrophilic Gel-lubricant | Glycerin based gel | - | Same |

| | | | |
|---|---|---|---|
| Tip Configuration | Straight tip<br>Olive Coudé tip<br>Tapered Coudé tip | Same | Same |
| Catheter Outer Diameter | CH08 – CH16 | CH05 – CH 18 | Same |
| Urine Bag | PVC with DEHT | - | PVC with DEHP |
| Urine Bag Components: Introducer Tube | PVC with DINCH | - | PVC with DEHP |
| Urine Bag Components: Introducer Tip | PVC with DEHT | - | PVC with DEHP |

Performance Data:

Performance testing for Self-Cath Closed System was conducted per applicable sections of non-recognized and recognized voluntary consensus standards, as well as established internal methods. The following tests were completed to determine the impact of the proposed material change based on assessment of the device risk documentation:

- Biocompatibility testing and toxicological risk assessment based on chemical analysis according to ISO 10993-1:2018 and FDA Guidance "Use of International Standard ISO 10993-1" (2020)
- Catheter performance according to ISO 20696:2018 (e.g. Effective Length, Verification of Catheter Surface Finish, Verification of Catheter Effective Shaft Length) and EN ISO 8669-2:1996 for Urine collection bags (Rated Volume, Strength of Attachment of the inlet tubing)
- Packaging sterile barrier integrity testing per ISO 11607-1
- Accelerated and Real Time aged shelf-life testing according to ASTM F1980-16

All tests met the pre-determined acceptance criteria.

**Conclusion:**

The performance testing demonstrates the subject devices are as safe and effective as the predicate devices.