December 2, 2022

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

Re: K221401
Trade/Device Name: Self-Cath and Self-Cath Plus
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZD
Dated: November 3, 2022
Received: November 4, 2022

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,

Negeen Haghighi -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

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)*
K221401

Device Name
Self-Cath and Self-Cath Plus

Indications for Use *(Describe)*
Self-Cath and Self-Cath Plus are 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5. TRADITIONAL 510(K) SUMMARY

Submitted by: Coloplast A/S
Holtedam1
3050 Humlebaek
Denmark

Contact Person : Preeti Jain
Head of Regulatory Affairs, North America
Coloplast
1601 West River Road North
Minneapolis MN 55411
Phone: +1 (612)-413-5614
Email: uspj@coloplast.com

Date of Summary: December 2, 2022

Subject Device:

Trade or Proprietary Name: Self-Cath and Self-Cath Plus

Item/Model Numbers: Self-Cath: 110, 112, 114, 116, 208, 210, 212, 214, 240, 305, 306, 308, 310, 408, 410, 412, 414, 416, 418, 450, 460, 608, 610, 612, 614, 806, 808, 810, 812, 814, 816, 818, 50201, 50202, 50203, 50204

Self-Cath Plus: 4110, 4112, 4114, 4116, 4210, 4212, 4214, 4306, 4308, 4310, 4408, 4410, 4412, 4414, 4416, 4418, 4608, 4610, 4612, 4614, 4808, 4810, 4812, 4814, 4816

Common or Usual Name: Intermittent Catheter, Urethral

Regulation/Classification Name: Urological Catheter and Accessories

Regulation/Classification Number: 21 CFR 876.5130

Product Code: EZD

Product Code Name: Catheter, Straight

Review Panel:	Gastroenterology/Urology
Predicate Device:	Self-Cath, K100878 The predicate device has not been subject of a design-related recall.
Reference Device:	Self-Cath Plus, K003784 The reference device has not been subject of a design-related recall.
Device Description:	**Self-Cath** and **Self-Cath Plus** devices are single-use, sterile catheters for intermittent urinary catheterization. Self-Cath is an uncoated catheter and Self-Cath Plus has a hydrophilic-coating. The catheters are sterilized by ethylene oxide (EO).
Indications for Use:	**Self-Cath** and **Self-Cath Plus** are 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. The subject and predicate devices have the same intended use.
Technological Characteristics:	The subject devices have the same intended use, indications for use, catheter size, principles of operation, technological characteristics, and performance specifications as the predicate device. The difference between the subject devices and predicate device is as below: • The polyvinyl chloride (PVC) catheter and connector in the subject devices contain Bis(2-ethylhexyl) terephthalate (DEHT) softener (phthalate) • The predicate device contains Bis(2-ethylhexyl) phthalate (DEHP) softener. The difference in technological characteristics (softener) do not raise different questions of safety and effectiveness.

Performance Data:

Performance testing for Self-Cath and Self-Cath Plus 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 according to FDA Guidance "Use of International Standard ISO 10993-1" (2020).
- Catheter performance according to ISO 20696:2018, ASTM F623-99:2013, and ASTM D1894:2014.
- 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 device.