September 21, 2022

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

Re: K222059
Trade/Device Name: SpeediCath Flex Set
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: July 12, 2022
Received: July 13, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222059

Device Name
SpeediCath Flex Set

Indications for Use *(Describe)*
SpeediCath Flex Set is indicated for use by patients with urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

The product is for male patients only.

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."

5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person:	Preeti Jain Head of Regulatory Affairs Coloplast Corporation 1601 West River Road North Minneapolis MN 55411 Phone: +1 612-413-5614 Email: uspj@coloplast.com
Date of Summary:	September 19, 2022
Trade or Proprietary Name:	SpeediCath Flex Set
Common or Usual Name:	Catheter, Urethral
Classification Name:	Urological Catheter and Accessories
Classification:	Class II
Regulation Number:	21 CFR 876.5130
Product Code:	EZD
Review Panel:	Gastroenterology/Urology
Predicate Device:	SpeediCath Flex Coudé Pro, K190620. The predicate device has not been subject to a design-related recall.
Reference Device:	SpeediCath Compact Set, K121458.
Device Description:	The SpeediCath Flex Set is a sterile, single use hydrophilic coated polyurethane catheter for men with an integrated collection bag (urine bag) which provides ease of use during collection and emptying of urine. The catheter is to be used for intermittent drainage of the bladder through the urethra by adult males with missing or reduced bladder control. The catheter has a protective sleeve which serves as protection from the user's touch and aids the user during insertion of the catheter into the urethra. The device is intended for use by prescription only. The device comes in FR size 10, 12, 14, and 16; corresponding to model numbers 28931, 28932, 28934, and 28936 respectively.

Indications for Use:

SpeediCath Flex Set is indicated for use by patients with urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

The product is for male patients only.

Technological Characteristics:

The subject device has the same intended use, indications for use, catheter sizes, technological characteristics, principles of operation, and performance specifications as the predicate device. The subject device shares the same catheter as previously cleared SpeediCath devices (K161671 and K190620). The subject device has the same hydrophilic coating, swelling medium (wetting agent), protective sleeve, and primary packaging as the predicate device.

The differences between the subject device and predicate device are in the following:

- The subject device contains a 1,000 mL collection bag (urine bag) which is attached to the catheter connector via a bag connector.
- A cap has been added to the subject device which connects to the handle and seals the catheter and wetting agent in the protective sleeve.
- The subject device outer connector is white, whereas the predicate device outer connector is turquoise.
- The subject device has a flexible, straight tip. The predicate device has a flexible, bended (Coudé) tip.

The difference in technological characteristics do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Testing / Performance Data:

Performance testing for SpeediCath Flex Set was conducted according to the applicable sections of non-recognized and recognized voluntary consensus standards, as well as established internal methods.

The performance of SpeediCath Flex Set met the requirements of:

- ISO 8669-2:1996 Urine collection bags - Part 2: Requirements and test methods
- ISO 20696:2018: Sterile urinary catheters and accessory devices for single use
- ASTM F623-99:2013: Standard Performance Specification for Foley Catheters (Flow rate only)
- D1894:2014: Coefficient of friction
- Usability per ISO 62366-1:2015, AAMI HE 75:2009 and FDA Guidance "Applying Human Factors and Usability Engineering to Optimize Medical Device Design, February 3, 2016"
- Biocompatibility according to ISO 10993-1 (2018) and FDA Guidance "Use of International Standards ISO 10993-1" (2020)
- ASTM D4169: Standard Practice for Performance Testing of Shipping Containers and Systems
- Real Time and Accelerated Aging shelf life testing according to ASTM F1980-16
- Internal requirements for break-off tap force, cap/handle opening torque, drip-tight closure of handle and cap, pH and Osmolality of the wetting agent/hydrophilic coating, and protective sleeve welding strength

All tests met the pre-determined acceptance criteria.

Conclusion:

The performance testing demonstrates the subject device is as safe and effective as the predicate device.