April 26, 2022

Coloplast
Delaney McDougal
Sr. Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K210250
Trade/Device Name: SpeediCath Compact
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: March 18, 2022
Received: March 21, 2022

Dear Delaney McDougal:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210250

Device Name
SpeediCath Compact

Indications for Use *(Describe)*

The catheter is indicated for use by patients with chronic urine retention and patients with a 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 the urine to drain.

The catheter is intended for males 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.

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TRADITIONAL 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person :	Delaney McDougal Senior Regulatory Affairs Specialist Coloplast 1601 West River Road North Minneapolis, MN 55411 Phone: +1 612-380-8034 Email: usdel@coloplast.com
Date of Summary:	April 21, 2022
Trade or Proprietary Name:	SpeediCath Compact
Item Numbers:	28692, 28702
Common or Usual Name:	Catheter, Urethral
Regulation Name:	Urological Catheter and Accessories
Regulation Number	21 CFR 876.5130
Device Class:	Class II
Product Code:	EZD
Review Panel:	Gastroenterology/Urology
Predicate Device:	SpeediCath Compact Male, K143182 The predicate device has not been subject to a design-related recall.

Device Description:

The SpeediCath Compact Male is a sterile, ready to use intermittent catheter for males. It is a single use catheter and is sterilized using E-beam Irradiation.

The catheter is a hollow polyurethane tube that facilitates drainage of urine from the bladder through the urethra. SpeediCath Compact Male is available in one size FR/CH 12/18 and is for male users only.

The catheter is hydrophilic coated and placed in a sterile solution (swelling medium) inside a tube, which together with a closure and plug make up the primary packaging and the sterile barrier.

Indications for Use:

The catheter is indicated for use by patients with chronic urine retention and patients with a 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 the urine to drain.

The catheter is intended for males only.

The subject and predicate devices have the same intended use.

Technological Characteristics:

The subject device has 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 device and predicate device is in the following:

- Swelling medium in the subject device contains polyethylene glycol (PEG); the predicate contains polyvinylpyrrolidone (PVP).

The swelling medium resides between the catheter and the inner tube and lubricates the catheter coating.

The difference in technological characteristics (the swelling medium) do not raise different questions of safety and effectiveness.

Performance Data:

Performance testing for SpeediCath Compact Male was conducted per applicable sections of voluntary and FDA consensus standards:

- Biocompatibility testing (cytotoxicity, irritation, sensitization, material mediated pyrogenicity 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)
- Coefficient of friction according to ASTM D1894:2014
- Accelerated and Real Time aged shelf-life testing according to ASTM F1980-16
- Sterilization dose setting according to ISO 11137-1:2015 and ISO/TS 13004:2013

The following tests were completed using established methods to determine the impact of the swelling medium modification based upon assessment of the risk documentation:

- Catheter coating - dry out in air: to measure the friction 5 minutes after the catheter has been opened and removed from the primary packaging. As the user might not insert the catheter immediately after opening, the test is performed to verify that the coating after the catheter has been exposed to air in 5 minutes is still lubricated and not dry at insertion.
- Catheters, objective friction measurement: to measure the friction of the catheter immediately after opening and removal from the primary packaging. After removal from the primary packing, the catheter is no longer immersed in swelling medium and ready for use.
- pH of the swelling medium: to measure the pH of swelling medium using a calibrated pH measure.
- Osmolality of the swelling medium: to measure salt/molecules in the swelling medium using an osmometer.

Conclusion:

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