March 8, 2022

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

Re: K203637
Trade/Device Name: SpeediCath Compact
SpeediCath Compact Plus
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: February 4, 2022
Received: February 8, 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)*
K203637

Device Name
SpeediCath Compact and SpeediCath Compact Plus

Indications for Use *(Describe)*
SpeediCath Compact and SpeediCath Compact Plus 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 urine to drain. The product is indicated for female patients only (adults and children of and above the age of 2 years). Choice of model and size of the catheter for the individual patient is made upon recommendation by the local health care professional.

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

1. Submitter Information

510 (k) submitter	Coloplast A/S
Address	Holtedam 1 3050 Humlebaek Denmark
Contact Person	Delaney McDougal Senior Regulatory Affairs Specialist Coloplast 1601 West River Road North Minneapolis, MN 55411 Telephone : 612-380-8034 Email : usdel@coloplast.com
Preparation date	March 07, 2022

2. Device Name

Trade Name of the Device	SpeediCath Compact SpeediCath Compact Plus
Common Name	Catheter, Straight
Classification Name	Urological Catheter and Accessories
Classification Regulation	21 CFR 876.5130
Device Class	II
Panel	Gastroenterology/Urology
Product Code	EZD

3. Predicate Device

Owner	Coloplast Corp.
Trade Name of the Device	SpeediCath Compact
Classification Name	Urological Catheter and Accessories
Regulation Classification	21 CFR 876.5130
Device Class	II
Panel	Gastroenterology/Urology
Product Code	GBM
510(k) Number	K072808

4. Device Description

The SpeediCath Compact and SpeediCath Compact Plus are sterile, ready to use intermittent catheters for females. These are single use catheters. The subject catheters have a hollow polyurethane inner tube that facilitates drainage of urine from the bladder through the urethra. SpeediCath Compact is available in size FR/CH 8, FR/CH 10, FR/CH 12, and FR/CH 14. SpeediCath Compact Plus is 2 cm longer than SpeediCath Compact and is available in FR/CH 10, FR/CH 12, and FR/CH 14. The catheter is hydrophilic coated and placed in a sterile solution (swelling medium) inside the inner tube, which together with a handle and plug make up the primary packaging and the sterile barrier.

After inserting the catheter through the urethra and into the bladder, urine flows through the polished eyelets (holes) at the tip of the catheter, the handle, and the plug. The hydrophilic coating on the catheter, as well as the swelling medium, provide a lubricated surface for minimized friction through the urethra.

5. Indication For Use

SpeediCath Compact and SpeediCath Compact Plus 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 urine to drain. The product is indicated for female patients only (adults and children of and above the age of 2 years). Choice of model and size of the catheter for the individual patient is made upon recommendation by the local health care professional.

6. Comparison of the Technological Characteristics with Predicate Device

Device & Predicate Device(s):	**K203637**	**K072808**	
General Device Characteristics			
Device Name	SpeediCath Compact and SpeediCath Compact Plus	SpeediCath Compact	
Device Type	Intermittent Urinary Drainage catheter	Intermittent Urinary Drainage catheter	*same*
Indication for Use	SpeediCath Compact and SpeediCath Compact Plus 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 urine to drain. The product is indicated for female patients only (adults and children of and above the age of 2 years). Choice of model and size of the catheter for the individual patient is made upon recommendation by the local health care professional.	Speedicath compact 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 urine to drain. The catheter is for female patients only.	*similar, clarification patient population added*
Design	This catheter is a hollow polyurethane inner tube with a hydrophilic coating.	This catheter is a disposable polyurethane catheter for females. The catheter is pre-lubricated with a hydrophilic coating.	*same*

Catheter Material	Polyurethane	Polyurethane	*Same*
Swelling Medium	Polyethylene Glycol (PEG)	Polyvinyl Pyrrolidone (PVP)	***different***
Catheter French Size	SpeediCath Compact is available in size FR/CH 8-14. SpeediCath Compact Plus is available in FR/CH 10-14.	SpeediCath Compact is available in size FR/CH 8-14.	*similar*
Hydrophilic coating	Polyvinylpyrrolidone	Polyvinylpyrrolidone	*same*
Storage	Exposure to extreme temperatures (-18°C and up to 60°C) for up to 24 hours will not damage the product.	Exposure to extreme temperatures (below 0°C and up to 60°C) for up to 24 hours will not damage the product.	*similar*
Provided Sterilized	Yes	Yes	*same*
User environment	In presence of healthcare professional or self (after getting trained by a healthcare professional)	In presence of healthcare professional or self (after getting trained by a healthcare professional)	*same*
Rx/OTC	Rx	Rx	*same*

The subject device has the same intended use as the predicate device. As evidenced from the above table, the only difference between the subject device and predicate device is that the 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 activates the hydrophilic coating to create a lubricated surface. However, performance testing was conducted on the subject catheter, and it was established that the difference in swelling medium between the subject and the predicate does not raise different questions of safety or effectiveness.

7. Performance Data

Below is a list of the tests that have been performed and successfully completed for the subject catheter:

- Biocompatibility testing (cytotoxicity, irritation, sensitivity, pyrogenicity and chemical characterization) according to ISO 10993-1:2018 and FDA Guidance “Use of International Standard ISO 10993-1” (2016)
- 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. The results showed that the subject catheter met all the requirements:

- Catheter coating - dry out in air
- Catheters, objective friction measurement
- pH of the swelling medium
- Osmolality of the swelling medium

8. Conclusion

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate. .