November 13, 2020

Coloplast
Michael Bumgarner
Principal Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K200820
Trade/Device Name: SpeediCath Compact Set
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: October 2, 2020
Received: October 5, 2020

Dear Michael Bumgarner:

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,

Sharon M. Andrews
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)*

K200820

Device Name
SpeediCath Compact Set

Indications for Use *(Describe)*

SpeediCath Compact Set 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. This device 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.

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5.0 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person :	Michael Bumgarner Principal Regulatory Affairs Specialist Coloplast 1601 West River Road North Minneapolis, MN 55411 612-263-0488 usmbum@coloplast.com
Date of Summary:	13 November 2020
Trade or Proprietary Name:	SpeediCath Compact Set
Common or Usual Name:	Catheter, Urethral
Classification Name:	Urological Catheter and Accessories
Regulation Number	21 CFR 876.5130
Classification:	Class II
Product Code:	GBM (Catheter, urethral)
Review Panel:	Gastroenterology/Urology
Predicate Device:	SpeediCath Compact Set, K121458 The predicate device has not been subject to a design related recall.

Device Description:

The SpeediCath Compact Set is a sterile, ready to use intermittent catheter for males. It is a single use catheter with an integrated urine bag.

The catheter is a hollow tube consisting of polyurethane and methylmethacrylate–acrylonitrilebutadiene-styrene polymer [MABS]. It facilitates drainage of urine from the bladder through the urethra to the collection bag. It is available in one size FR/CH 12/18.

The catheter is hydrophilic coated and placed in a sterile solution (swelling medium) containing polyethylene glycol (PEG) inside a tube. The swelling medium resides between the catheter and the tube and lubricates the catheter.

Indications for Use:

SpeediCath Compact Set 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.

This device is intended for males only.

The subject and predicate devices have the same intended use.

Comparison of Technical Characteristics:

The subject device and predicated device have different technological characteristics as follows:

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

The different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing:

Performance testing for SpeediCath Compact Set was conducted per applicable sections of voluntary and FDA consensus standards and the results were acceptable:

- Biocompatibility testing (cytotoxicity, irritation, sensitivity, 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
- Corrosion according to EN ISO 20696:2018 and EN 1616 :1997
- 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 and the results were acceptable:

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

Conclusion:

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