October 25, 2018

Coloplast
Troy Thome
Senior Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, Minnesota 55411

Re: K180258
Trade/Device Name: SpeediCath Standard
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: GBM
Dated: September 21, 2018
Received: September 24, 2018

Dear Troy Thome:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K180258

Device Name
SpeediCath Standard

Indications for Use *(Describe)*
Urinary catheter for intermittent 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.

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.

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SpeediCath Standard
510(k) Summary

Submitted by:	Coloplast Corp 1601 West River Road North Minneapolis, MN 55411 USA
Contact Person:	Troy Thome Coloplast Corp Phone : 612-704-9909 Fax : 612-287-4138 Email : ustthome@coloplast.com
Date of Summary:	October 24, 2018
Trade or Proprietary Name:	SpeediCath® Standard
Common or Usual Name:	Catheter, urethral
Classification Name:	Urological catheter and accessories 21CFR 876.5130
Classification:	Class II
Product Code:	GBM
Predicate Device:	SpeediCath, K023254 (Manufacturer: Coloplast)
Device Description:	The SpeediCath Standard is a sterile single use hydrophilic coated polyurethane catheter. The catheter is placed in a swelling media, packed and sealed in a foil pouch and sterilized.
Indication for Use:	Urinary catheter for intermittent 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.
Technological Characteristics:	The subject device has the same indications for use, design, materials (with exception of the swelling media that lubricates the catheter) and principles of operations as the predicate device. The subject device includes the same coating and packaging configuration.

Summary of Non-Clinical Testing:	Performance testing for SpeediCath Standard was conducted according to applicable sections of voluntary standards: • Biocompatibility testing according to ISO 10993-1:2009 and FDA Guidance "Use of International Standard ISO 10993-1" (2016) was completed. • Bench testing was completed per ASTM D1894:2014 and internal test methods. • Accelerated Aged (in compliance with ASTM F1980-16) shelf life testing was completed. • Sterilization dose confirmation was completed according to ISO 11137-2: 2013. All tests met the pre-determined acceptance criteria.
Substantial Equivalence Conclusion:	The SpeediCath Standard is as safe and effective and is substantially equivalent to the legally marketed predicate device as demonstrated by the same intended use, same principles of operation, similar technological characteristics and performance data, and does not raise different questions of safety and effectiveness.