February 2, 2018

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

Re: K180070
Trade/Device Name: SpeediCath Flex Coudé Pro
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: January 8, 2018
Received: January 9, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

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)*

K180070

Device Name
SpeediCath Flex Coudé Pro

Indications for Use *(Describe)*

The SpeediCath Flex Coudé Pro is indicated for use by patients with 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 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.

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4.0 SPECIAL 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:	08 January 2018
Trade or Proprietary Name:	SpeediCath Flex Coudé Pro
Common or Usual Name:	Catheter, urethral
Classification Name:	Urological catheter and accessories 21CFR 876.5130
Classification:	Class II
Product Code:	GBM
Predicate Device:	SpeediCath Flex Coudé, K161672 (Manufacturer: Coloplast)
Device Description:	The SpeediCath Flex Coudé Pro catheter is a sterile single use hydrophilic coated polyurethane catheter for men. The catheter is to be used for intermittent drainage of the bladder through the urethra by males with missing or reduced bladder control. The catheter has a bended flexible tip that facilitates passage through the urethra to the bladder. The catheter is shielded by a sleeve, which serves as protection from the user's touch during insertion.
Indication for Use:	SpeediCath Flex Coudé Pro 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 indications for use, design, sizes, materials and principles of operations as the predicate device. The subject device includes the same coating and saline solution (prelubrication), sleeve and packaging configuration. The subject device has the same degree of tip flexibility as the predicate device which allows the tip of the catheter to achieve different degrees of curvature.

The differences between the subject device and predicate device is that the predicate device (SpeediCath Flex Coudé) has a straight flexible tip whereas the subject device has a pre-formed flexible bended tip. Under straight urethral passages, both variants show a straight profile, acting as a Nelaton tip, whereas when passing through difficult passages the tip of both variants will bend progressively and adopt the curved profile of a Coudé tip. This enables and facilitates passage through difficult, curved anatomies.

Summary of Non-Clinical Testing:

Performance testing for SpeediCath Flex Coude Pro was conducted according to applicable sections of voluntary standards in order to document the following properties of the SpeediCath Flex Coudé Pro catheter. The proposed changes do not impact the performance testing:

- Flow rate according to EN1616/EN1618 & ASTM F623-99:2013
- Coefficient of friction according to ASTM D1894:2014
- Tensile strength according to EN1616/EN1618.
- Connector security according to EN1616.
- Biocompatibility according to ISO 10993-1 (2009) and FDA Guidance “Use of International Standard ISO 10993-1” (2016)

The following tests were completed to determine the impact of the modification based on assessment of the device risk documentation:

- Coating inspection at average and extreme temperatures according to internal test methods.
- Tip bend inspection at extreme temperature according to internal test methods.
- Biocompatibility assessment per ISO 10993-1: 2009
- Accelerated Aged (per ISO F1980-16) shelf life testing per internal test method assessments for coating and tip bend inspections.

All tests passed the pre-determined acceptance criteria.

Substantial Equivalence Conclusion:

Based on the performance testing conducted, the modified device intended as a line extension, SpeediCath Flex Coude Pro, is as safe and effective and performs equivalent to the predicate device.