July 10, 2019

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

Re: K190620
Trade/Device Name: SpeediCath Flex Coude Pro
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: Class II
Product Code: GBM
Dated: May 29, 2019
Received: May 30, 2019

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,

for
Glenn B. Bell, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190620

Device Name

SpeediCath Flex Coudé Pro

Indications for Use *(Describe)*

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510(K) SUMMARY

Submitted by:	Coloplast Corp 1601 West River Road North Minneapolis, MN 55411 USA
Contact Person :	Ms. Delaney McDougal Coloplast Corp Phone :+1 612-380-8034 Email: usdel@coloplast.com
Date of Summary:	July 10, 2019
Trade or Proprietary Name:	SpeediCath Flex Coude′ Pro
Common or Usual Name:	Catheter urethral
Regulation Name:	Urological catheter and accessories
Device Class:	Class II
Regulation Number:	21CFR 876.5130
Product Code:	GBM
Review Panel:	Gastroenterology/Urology
Predicate Device:	SpeediCath Flex Coude′ Pro: K180070 Reference device: SpeediCath Standard: K180258
Device Description:	The SpeediCath Flex Coude′ 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 form the user's touch during insertion. The SpeediCath Flex Coude′ Pro Catheters are offered with a 33cm effective length and range in size from 10Fr to 16Fr. The hydrophilic coating makes this single use catheter ready to use.
Indication for Use:	SpeediCath Flex Coude′ 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, catheter French sizes and lengths, and principles of operations as the predicate device. The device includes the same raw catheter coating and sleeve design.

The differences between the subject device and predicate device is in the following:

- Pouch material and dimensions
- Sleeve material and dimensions
- Wetting agent material and volume
- Product variants – line extension

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 Coude′ Pro catheter.

- Accelerated Aged (per ISO F1980-16) shelf life testing for coating and tip bend inspections
- Biocompatibility according to ISO 10993-1 (2009) and FDA Guidance "Use of International Standards ISO 10993-1" (2016)
- Coefficient of friction according to ASTM D1894: 2014
- Transportation testing per ASTM D4169 followed by assessments of coating performance and inspection of damage of packaging

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

- Catheter kink testing
- Catheter tip integrity
- Coating inspection
- Proof of packing seal
- Peel force test of new material to test for ability to open packaging

The following performance specifications for SpeediCath Flex Coude′ Pro were established based on performance testing of the predicate device according to applicable sections of voluntary standards.

- Flow rate according to EN1616/EN1618 and ASTM F623-99: 2013
- Tensile strength according to EN1616/EN1618
- Connector security according to EN1616

All tests passed the pre-determined acceptance criteria. The proposed changes do not impact the performance specifications.

Substantial Equivalence Table:

Item	Subject Device	Predicate Device
Indications for Use	SpeediCath Flex Coude′ Pro is indicated for use by patients with urine retention and patients with post void residual volume (PVR) due to neurogenic and nonneurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The product is for male patients only.	SpeediCath Flex Coude′ 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.
Sterility	E-beam	E-beam
Configuration	Tip: flexible bended tip	Tip: flexible bended tip
Materials	*Catheter*: Polyurethane *Hydrophilic coating*: PVP based *Wetting agent*: PEG *Protective sleeve*: color pigment, polyethylene styrene isobutylene copolymer *Pouch*: Polyethylene & PETP	*Catheter:* Polyurethane *Hydrophilic coating*: PVP based *Wetting agent*: PVP *Protective sleeve*: color pigment and polyethylene *Pouch*: Polyethylene & PETP/aluminum
Pouch Configurations	Single & double-loop (pocket-size) Dimension: Single: 249 mm L x 100mm W Double: 186 mm L x 87 mm W	Single-loop Dimension: 216 mm L 100 mm W
Biocompatibility	Per ISO 10993	Per ISO 10993
Friction	Per ASTM D 1894-14	Per ASTM D 1894-14
Flow rate	Per ASTM F 623-99	Per ASTM F 623-99
Tensile	Per EN 1616/1618	Per EN 1616/1618
Shelf life	2 years	2 years
Available sizes	Fr 10 – 16 single-loop Fr 10 – 14 double-loop	Fr 10 – 16 single-loop

Substantial Equivalence Conclusion:

Based on the intended use, technological characteristics, safety and performance testing included in this submission, Coloplast considers the Product to be substantially equivalent to the currently marketed SpeediCath Flex Coude′ Pro.

The SpeediCath Flex Coudé Pro differs from the predicate device in regards to the protective sleeve, primary packaging pouch, wetting agent, and product size variants. The protective sleeve has been updated to a larger overall width to accommodate additional wetting agent. The primary packaging pouch length was increased to allow for additional space inside the pouch for the product, the pull-tab from the predicate product has been removed and replaced with a circular hole in order to provide ease of opening for users with limited dexterity, and the aluminum layer within the pouch has been replaced with a PET layer in order to improve the environmental impact. The wetting agent used within the protective sleeve was updated from PVP water to PEG water which is currently used within the predicate device. The product line has been updated to make available a double-loop (pocket-size) variation which is currently available in the predicate device.