July 30, 2020

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

Re: K200142
Trade/Device Name: SpeediCath Soft
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: Class II
Product Code: GBM
Dated: July 17, 2020
Received: July 22, 2020

Dear Ms. 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,

Purva Pandya
Acting 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)*
K200142

Device Name
SpeediCath Soft

Indications for Use *(Describe)*
SpeediCath Soft 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 adult 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.

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5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person:	Ms. Delaney McDougal Senior Regulatory Affairs Specialist Coloplast 1601 West River Road North Minneapolis, MN 55411 612-380-8034 usdel@coloplast.com
Date of Summary:	January 21, 2020
Trade or Proprietary Name:	SpeediCath Soft 27010, 27012, 27014, 27016
Common or Usual Name:	Catheter, Urethral
Classification Name:	Urological Catheter and Accessories
Classification:	Class II
Regulation Number:	21 CFR 876.5130
Product Code:	GBM
Review Panel:	Gastroenterology/Urology
Predicate Device:	SpeediCath Flex Coudé Pro, K190620 Reference Device: SpeediCath Standard, K180258

Device Description:	The SpeediCath Soft 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 adult males with missing or reduced bladder control. The catheter has a grip which serves as protection from the user's touch and aids the user during insertion.
Intended Use:	Intermittent urinary drainage catheter
Indications for Use:	SpeediCath Soft 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 adult male patients only.
Technological Characteristics:	The subject device has the same intended use, indications for use, catheter sizes, technological characteristics, principles of operation, and performance specifications as the predicate device. The subject device includes the same catheter material, swelling medium (wetting agent), and hydrophilic coating as the predicate device. The differences between the subject device and predicate device are in the following: • The subject device contains a grip, instead of a protective sleeve as with the predicate device, which protects the catheter from direct contact with the user's touch and aids the user during insertion of the catheter. The material of the grip is the same material as the predicate device handle and connector (K190620). • The subject device has a straight tip design instead of a pre-formed flexible curved tip (bended). The straight tip design was previously cleared under the reference device, K180258. The tip is composed of the same material as the catheter of the predicate device, (K190620). • The subject device has a color-coded outer connector to aid in the identification of catheter sizes. The color-coded outer connectors are identical to the connectors of the reference device (K180258). • The primary packaging design of the subject device is a foil pouch consisting of a top foil (layers of

polyamide/aluminum/polyamide) and a bottom foil (layers of polyamide/aluminum/low-density polyethylene) that are welded together which provides the sterile barrier of the device and contains a proof of seal for detection of the non-broken sterile barrier. The thickness of the aluminum layers in the top and bottom foils of the subject device packaging has been reduced in comparison to the reference device packaging (K180258) to improve the environmental footprint and cost-effectiveness of the packaging. The opening feature pull-ring was updated to an oval shape, versus a ring shape as with the reference device (K180258), for ease of opening. The primary packaging color, the print tape color and wall sticker dimensions and color were updated as part of a packaging alignment across the SpeediCath portfolio. The primary packaging configuration and dimensions are identical to those of the reference device packaging cleared under K180258.

- The subject device has 10 mm distance between the drainage eyelets, whereas the reference device K180258, SpeediCath Standard, has 12 mm between eyelets. Additionally, the length from the edge of the first eyelet to the catheter tip (tip length) and the length from the bottom edge of the grip to the first eyelet (draining length) varies with the catheter size.

Comparison to the predicate device is provided in the Substantial Equivalence Table below.

Substantial Equivalence Table

	Subject device	Predicate device	Reference device
Product	**SpeediCath Soft**	**SpeediCath Flex Coudé Pro**	**SpeediCath Standard**
510(k) Number	Unassigned	K190620	K180258
Regulation Name	Urological catheter and accessories	Same	Same
Regulation Number	21 CFR 876.5130	Same	Same
Product Code	GBM	Same	Same
Classification	II	Same	Same
Prescription Device	Yes	Same	Same
Intended Use	Urinary catheter for intermittent use	Same	Same
Indications for Use	SpeediCath Soft 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 adult male patients only.	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.	Urinary catheter for intermittent use. The catheter is intended 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.
Condition of Use	Intermittent use and single use	Same	Same
Sterility	SAL 10^{-6}	Same	Same

	Subject device	Predicate device	Reference device
Product	**SpeediCath Soft**	**SpeediCath Flex Coudé Pro**	**SpeediCath Standard**
Sterilization Method	e-beam	Same	Same
Shelf Life	2 years	Same	Same
Available Sizes	FR 10 / CH 10 FR 12 / CH 12 FR 14 / CH 14 FR 16 / CH 16	Same	Male, FR 8 / CH 8 Male, FR 10 / CH 10 Male, FR 12 / CH 12 Male, FR 14 / CH 14 Male, FR 16 / CH 16 Male, FR 18 / CH 18 Tiemann, FR 10 / CH 10 Tiemann, FR 12 / CH 12 Tiemann, FR 14 / CH 14 Tiemann, FR 16 / CH 16 Female, FR 6 / CH 6 Female, FR 8 / CH 8 Female, FR 10 / CH 10 Female, FR 12 / CH 12 Female, FR 14 / CH 14 Female, FR 16 / CH 16 Boy, FR 6 / CH 6 Boy, FR 8 / CH 8 Boy, FR 10 / CH 10 Boy, FR 12 / CH 12 Pediatric, FR 6 / CH 6 Pediatric, FR 8 / CH 8 Pediatric, FR 10 / CH 10
Catheter Outer Diameter	FR 10 / CH 10: 3.3 mm FR 12 / CH 12: 4.0 mm FR 14 / CH 14: 4.7 mm FR 16 / CH 16: 5.3 mm	Same	Same (male models)
Catheter Materials	Polyurethane	Same	Similar

	Subject device	Predicate device	Reference device
Product	**SpeediCath Soft**	**SpeediCath Flex Coudé Pro**	**SpeediCath Standard**
Catheter Material Flexural Modulus	4200 psi	Same	10990 psi
Hydrophilic Coating	Polyvinylpyrrolidone (PVP) based	Same	Same
Wetting Agent	Saline solution with PEG	Same	Same
Wetting Agent Amount	5.5±0.5 mL (all sizes)	15±0.5 mL (all sizes)	Same
Tip Configuration	Straight (Nelaton) tip	Flexible curved tip (bended)	Straight (Nelaton) tip and Tiemann tip
Straight Tip Eyelets	10 mm distance between eyelets	NA	12 mm distance between eyelets
Protective Sleeve Material	N/A	Color pigment Master Batch, polyethylene, and styrene isobutylene copolymer (two layers in middle)	N/A
Grip	Material: Thermolast M TM7MED linear low-density polyethylene (LLDPE) Master Batch 6% turquoise 0A500342M	N/A	N/A
Connector	Color-coded, FR / CH 10: Black FR / CH 12: White FR / CH 14: Green FR / CH 16: Orange	Turquoise and White (all sizes)	Same
Primary Packaging	Foil pouch, thinner, white	Single and double-loop pouch packages, gray	Similar, thicker, green

	Subject device	Predicate device	Reference device
Product	**SpeediCath Soft**	**SpeediCath Flex Coudé Pro**	**SpeediCath Standard**
Packaging Materials	Oriented polyamide, aluminum, and low-density PE, oval-shaped opening feature	Inner layer: PE-peel Outer layer: Printed PETP/aluminum	Oriented polyamide, aluminum, low-density polyethylene, ring-shaped opening feature
Packaging Dimensions	467 mm length 32 mm width	Large packaging (single-loop): 249 mm length 100mm width Small packaging (double-loop): 186 mm length 87 mm width	Same
Effective Catheter Length	Effective length (according to ISO 20696:2018): 33cm (13 inches)	Same	Same
Biocompatibility per ISO 10993	Complies	Same	Same
Low friction (ASTM D1894-14)	Complies	Same	Same
Flow rate (ASTM F623-99:2013)	Complies	Same	Same
Tensile Strength (DS/EN ISO 20696 Annex H)	Complies	Same	Same

Summary of Non-Clinical Testing / Performance Data:

Performance testing for SpeediCath Soft was conducted according to applicable sections of non-recognized and recognized voluntary consensus standards in order to document the following properties of the SpeediCath Soft catheter. The following tests were completed to determine the impact of the proposed features based on assessment of the device risk documentation. The proposed features do not impact the performance specifications:

- Real Time and Accelerated Aging shelf life testing according to ASTM F1980-16
- Biocompatibility according to ISO 10993-1 (2018) and FDA Guidance "Use of International Standards ISO 10993-1" (2016)
- Proof of packing seal strength and integrity
- Peel force test of packaging material
- Transportation testing per ASTM D4169 followed by assessments of coating performance and inspection of damage of packaging
- Detach and re-attach force of the grip
- Flow rate according to ASTM F623-99:2013 and ISO 20696:2018
- Coefficient of friction according to ASTM D1894:2014
- Catheter coating friction
- pH
- Osmolality
- Surface Finish according to ISO 20696:2018
- Outer Diameter according to ISO 20696:2018
- Effective Shaft Length according to ISO 20696:2018
- Catheter Strength according to ISO 20696:2018
- Connector Security according to ISO 20696:2018
- Kink Stability according to ISO 20696:2018
- Catheter Stiffness according to ISO 20696:2018
- Peak Tensile Force according to ISO 20696:2018
- Usability per EN 62366:2008, ISO 62366-1:2015, AAMI HE 75:2009 and FDA Guidance "Applying Human Factors and Usability Engineering to Optimize Medical Device Design, February 3, 2016"

All tests met the pre-determined acceptance criteria.

Substantial Equivalence Conclusion:

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

SpeediCath Soft differs from the predicate device in regard to the grip to aid insertion, the color-coded outer connector, primary packaging materials, and catheter tip. The grip protects the catheter from direct contact with the user's touch and aids the user during insertion of the catheter. The color-coded outer connector aids the user in the identification of catheter sizes. The primary packaging provides the sterile barrier of the device and contains a proof of seal for detection of the non-broken sterile barrier. The subject device has a straight tip whereas the predicate device has a pre-formed flexible curved tip (bended). The straight tip design was previously cleared under the reference device K180258. The described features do not raise any new questions of safety or effectiveness.