DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 29, 2016

Coloplast Corp.
Rebecca S. Roberts
Regulatory Affairs Manager
1601 West River Road North
Minneapolis, MN 55411

Re: K161672
Trade/Device Name: SpeediCath Flex Coudé
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: August 30, 2016
Received: September 1, 2016

Dear Rebecca S. Roberts:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161672

Device Name
SpeediCath Flex Coude'

Indications for Use *(Describe)*
The catheter 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 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.

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SpeediCath Flex Coudé
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Sponsor	Coloplast Corp 1601 West River Road North Minneapolis, MN 55411 USA
Contact Person	Rebecca S Roberts Coloplast Corp Phone 612-344-4987 Fax 612-287-4138 Email usrrob@coloplast.com
Date of submission	14 June 2016
Proprietary trade name	SpeediCath Flex Coudé
Classification name	Urological catheter and accessories
Classification	Class II
Product code	GBM

Legally Marketed predicate(s)	**Predicate device**	**Manufacturer**
	K023254, SpeediCath Standard	Coloplast A/S
	Reference device(s)	
	K090960, VaPro Intermittent	Hollister Inc.
	K143594, VaPro Pocket	Hollister Inc.

Product description	The SpeediCath Flex Coudé 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 flexible bendable 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 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.

Summary of technological characteristics	The subject device has similar indications for use, design, sizes materials and principles of operations as the predicate device SpeediCath Standard (K023254). The subject device includes the same coating and saline solution (pre-lubrication) as the predicate device. The differences between the subject device and predicate device are the protective sleeve, the packaging configuration and the flexible tip. The sleeve is for ease of use and hygienic insertion and is similar to the protective sleeve of the reference device VaPro Intermittent catheter (K090960). The packaging modifications are made for discretion improvements and are similar to the packaging configuration of reference device VaPro Pocket (K143594). The SpeediCath Flex Coudé catheter tip flexibility allows the tip of the catheter to achieve different degrees of curvature, rather than a fixed one as in the predicate and reference devices. Under straight urethral passages, the flexible tip will remain straight acting as a nelaton tip, whereas when passing through curvatures the tip will bend progressively and adopt the curved profile of a coudé tip. This enables and facilitates passage through difficult, curved anatomies, similar to the coudé tip (Tiemann variant) of the predicate device.
Performance data - bench	Performance testing was conducted according to applicable sections of voluntary standards in order to document the following properties of the SpeediCath Flex Coudé catheter: • 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 and applicable parts of FDA Blue Book Memorandum #G95-1. All tests passed.
Performance data – clinical	Based on the clinical evaluation of available published data it is evaluated that the SpeediCath Flex Coude' has a safety and efficacy profile equivalent to the predicate and reference devices. Furthermore, a pre-clinical study was performed using male cadavers with difficult urethral anatomies, resulting from enlarged prostate and strictures. SpeediCath Flex Coude' was comparable to a standard coude' catheter in terms of insertion and navigation through difficult male anatomies.
Conclusion	Based on the test results and additional supporting documentation provided in this premarket notification, the proposed device demonstrates substantial equivalence to the previously cleared predicate devices.