



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 2, 2015

Coloplast Corp.
Meg Daniel
Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K150935
Trade/Device Name: Speedicath Compact Eve
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: June 19, 2015
Received: June 22, 2015

Dear Meg Daniel,

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 yours,


Herbert P. Lerner -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

Statement of Indications for Use

510(k) Number (if known): ~~Not known~~ K150935

Device Name: **SpeediCath** Compact Eve

Indications for Use:

SpeediCath Compact Eve 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 urine to drain.

The catheter is for female patients only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

510(k) Summary

SpeediCath Compact Set

(as required per 21 CFR § 807.92)

The assigned 510(k) number is: K150935

Submitter: Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Contact Person: Megan Daniel
Regulatory Affairs Specialist
Coloplast Corp
1601 West River Road
Minneapolis, MN 55411
USA
Office: (612) 302-4930
Mobile: (612) 615-5088
Fax: (612) 287-4138
e-mail: usmeco@coloplast.com

Date Prepared: April 2, 2015

Device Name and Classification

Trade Name: **SpeediCath Compact Eve**
Common Name: Urinary Catheter for Intermittent Use
Classification Name: Urological catheters and accessories
Product Code: GBM

Legal Manufacturer

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

Device Description

The **SpeediCath** Compact Eve is a sterile, single use, disposable polyurethane catheter for females. The catheter is pre-lubricated with a hydrophilic coating and immersed in saline solution. In use, the handle is turned to break the packaging, connect a urine bag to the end of the handle, if required, and the catheter is pulled out of the packaging. The catheter is then ready to use allowing easy handling and urine to flow through the catheter and handle.

Substantial Equivalence Claim

Coloplast believes the proposed **SpeediCath** Compact Eve is substantially equivalent in form and function to Coloplast's **SpeediCath** Compact, which was cleared under 510(k) K072808 on November 9, 2007.

SpeediCath Compact Eve and the predicate device are sterile, single use catheters for intermittent use with hydrophilic coatings.

Both **SpeediCath** Compact Eve and **SpeediCath** Compact are ready to use catheters with hydrophilic coatings made of the same material and are both immersed in the same saline solution.

The difference between **SpeediCath** Compact Eve and the predicate device is the packaging configuration and visual appearance, a 2 cm longer catheter and the outlet, which can be connected to a urine bag. These modifications are made for ease of use and discretion improvements. The **SpeediCath** Compact Eve packaging configuration has the same ready to use features as the predicate, **SpeediCath** Compact, and is packaged in discrete containers.

SpeediCath Compact Eve and the predicate, **SpeediCath** Compact, are for females only.

Indications for Use

SpeediCath Compact Eve 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 urine to drain.

The catheter is for female patients only.

Summary of Testing

SpeediCath Compact Eve has been tested and complies with relevant sections of ASTM 623-99, ASTM D1894-11, EN 1616 and EN 1618.

SpeediCath Compact Eve has been tested and complies with relevant sections of ISO 10993, Biological Evaluation of Medical Devices.
