OCT 1 2012

510(k) Summary

SpeediCath Compact Set

(as required per 21 CFR § 807.92)

The assigned 510(k) number is: **K121458**

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

Contact Person: Brian E. Schmidt
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Coloplast Corp
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Date Prepared: September 25, 2012

Device Name and Classification

Trade Name: **SpeediCath** Compact Set

Common Name: Urinary Catheter for Intermittent Use

Classification Name: Gastroenterology-Urology Devices

Product Code: GBM

Legal Manufacturer / Manufacturing Site

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

Device Description

The **SpeediCath** Compact Set (Male) is a sterile, single use, disposable polyurethane catheter for males with a pre-attached urine collection bag. The catheter is pre-lubricated with a hydrophilic coating and immersed in saline solution. In use, the cover is removed, the bag is unfolded and the catheter is pulled out of the packaging thereby extending and locking it to its full length. The catheter with attached bag is then ready to use allowing easy drainage and collection of urine.

Substantial Equivalence Claim

Coloplast believes the proposed **SpeediCath** Compact Set is substantially equivalent in form and function to Coloplast's **SpeediCath**, which was cleared under 510(k) K023254 on January 27, 2003.

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

Both **SpeediCath** Compact Set and **SpeediCath** 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 Set and **SpeediCath** is the packaging configuration and material, the telescopic extension of the catheter as well as the addition of an attached urine collection bag. These modifications are made for discretion and ease of use improvements. The **SpeediCath** Compact Set packaging configuration has the same ready to use features as the predicate, **SpeediCath**, and is packaged in discrete containers. **SpeediCath** Compact Set is short in storage and is extended to its full length in use.

SpeediCath Compact Set is similar to other catheters, e.g. **Conveen EasiCath** Set (K973070), in that they both have a pre-attached bag for urine collection.

SpeediCath Compact Set is for males only while **SpeediCath** is available for males and females.

Indications for Use

SpeediCath Compact Set 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 device is intended for males only.

Summary of Testing

SpeediCath Compact Set has been tested and complies with relevant sections of ASTM 623, ASTM D1894, EN 1616, EN 1617, EN 1618 and ISO 8669-2.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast A/S
1601 West River Road North
MINNEAPOLIS MN 55411

OCT 1 2012

Re: K121458
Trade/Device Name: **SpeediCath** Compact Set
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: August 31, 2012
Received: September 5, 2012

Dear Mr. Schmidt:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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 K121458

Device Name: **SpeediCath** Compact Set

Indications for Use:

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The device is intended for males 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121458