510(k) Summary

SpeediCath Compact

(as required per 21 CFR § 807.92)

The assigned 510(k) number is: K072808

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

Contact Person: Rebeka A. Stoltman
Manager, Regulatory Affairs
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411

Telephone: (612) 302-4997
Facsimile: (612) 287-4138
Email: usrst@coloplast.com

NOV 0 9 2007

Date Prepared: September 28, 2007

Device Name and Classification

Trade Name:	**SpeediCath** Compact
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

SpeediCath Compact is a sterile, single use, disposable polyurethane catheter for females. The catheter is pre-lubricated with a hydrophilic coating and immersed in saline solution. The packaging of **SpeediCath** Compact is an integrated part of the product functioning partly as an insertion handle. In use, the inner tube is extended and removed from the handle as the catheter is locked in place with the handle. 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 is substantially equivalent in form and function to Coloplast's **SpeediCath**, which was cleared under 510(k) K023254 on January 27, 2003.

Both **SpeediCath** Compact and **SpeediCath** are ready to use intermittent catheters with hydrophilic coatings. The catheter and the hydrophilic coating are made of the same material and are both immersed in the same saline solution. They are both sold sterile and are single use.

The difference between **SpeediCath** Compact and **SpeediCath** is the packaging configuration and material, which have been modified for **SpeediCath** Compact for ease of use improvements. The **SpeediCath** Compact packaging configuration has the same ready to use features as the predicate, **SpeediCath**, but is shorter and packaged in pocket-size, single use containers. **SpeediCath** Compact is for female use only while **SpeediCath** is available for males and females.

Indications for Use

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

SpeediCath Compact 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
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

Ms. Rebeka Stoltman
Manager, Regulatory Affairs
Coloplast Corporation
1499 West River Road North
MINNEAPOLIS MN 55411

Re: K072808
Trade/Device Name: SpeediCath Compact
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: September 28, 2007
Received: October 5, 2007

Dear Ms. Stoltman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): ~~Not known~~ K072808

Device Name: **SpeediCath** Compact

Indications for Use:

SpeediCath Compact 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072808