K100878
Page 1 of 2

3. 510(K) SUMMARY

MAY 26 2010

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark
Phone/Fax/Email:	Office: (612) 302-4987 Mobile: (612) 968-9567 Fax: (612) 287-4138 e-mail: usbes@coloplast.com
Name of Contact Person:	Brian E. Schmidt Regulatory Affairs Manager
Address/Contact:	1601 West River Road Minneapolis, MN 55411
Date Prepared:	March 29, 2010
Trade Name:	Self Cath
Common Name:	Catheter, Urological
Classification Name:	21 CFR 876.5130 Gastroenterology-Urology Devices Class II
Product Code:	EZD

Legally Marketed Devices to Which Your Firm Is Claiming Equivalence:

The Self Cath Catheter is substantially equivalent in performance, indications, design and materials to Self Cath Plus cleared on March 5, 2001 under premarket notification 510(k) number K003784.

Description of the Device:

The **Self Cath Catheter** consists of a flexible PVC tube. One end of the tube has two holes (eyelets) punched into the tube. These eyelets allow urine to enter the tube and be drained from the bladder. A piece of PVC connector tubing (drain funnel) is attached to the opposite end of the PVC tube.

Intended Use Of The Device:

The **Self Cath Catheter** is intended for use in male, female, and pediatric patients (neonates, infants, children, adolescents, and transitional adolescents) requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Technological Characteristics Compared To Predicate Device:

The **Self Cath Catheter** is substantially equivalent to the Self Cath Plus catheter.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the **Self Cath Catheter** is supported by a comparison of the design, materials, and intended use compared to the predicates, as well as acceptable results from functional performance and biocompatibility testing.

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

MAY 26 2010

Re: K100878
Trade/Device Name: Self Cath® Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: May 18, 2010
Received: May 20, 2010

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.

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.

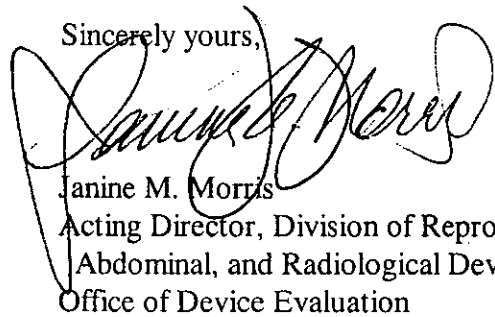
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K100878

Device Name: **Self Cath® Catheter**

Indications for Use:

The **Self Cath® Catheter** is intended for use in male, female, and pediatric patients (neonates, infants, children, adolescents, and transitional adolescents) requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K100878