K083770
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Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

NOV 23 2009

510(k) Summary

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark Establishment Registration: 9610694 Owner/Operator: 8010144
Phone/Fax/Email:	Office: (612) 287-4211 Mobile: (651) 387-1698 Fax: (612) 287-4138 email: usjco@coloplast.com
Name of Contact Person:	Janell A. Colley Regulatory Affairs Manager
Address/Contact:	1601 West River Road Minneapolis, MN 55411
Date Prepared:	August 20, 2009
Trade Name:	Peristeen™ Anal Irrigation System
Common Name:	Rectal Catheter and accessories and Enema kit
Classification Name:	876.5980 Gastrointestinal tube & accessories Class II and 876.5210 Enema kit Class I (Exempt)
Product Code:	KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:
The Peristeen Anal Irrigation System is substantially equivalent in performance, indications, design and materials to Zassi Medical Bowel Management System (BMS), cleared on November 6, 2002 under premarket notification 510(k) number K023344, and the Amsure Enema Cleansing Bag, a Class I (Exempt) Enema Kit per 21 CFR section 876.5210.

Description Of The Device:
The Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components. The PAI System is provided non-sterile and is latex free. It is intended for single patient use only.

Intended Use Of The Device:

The Peristeen Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Technological Characteristics Compared To Predicate Device:

The proposed Peristeen Anal Irrigation System is substantially equivalent to the Zassi Medical Bowel Management System (BMS) and to the Amsure Cleansing Enema Bag, Class I Exempt device.

Summary and Conclusions from the Nonclinical Tests Submitted:

Substantial equivalence of the Peristeen Anal Irrigation System 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

Coloplast A/S
c/o Ms. Janell A. Colley
Regulatory Affairs Manager
Coloplast Manufacturing US, LLC
1601 West River Road North
MINNEAPOLIS MN 55411

NOV 23 2009

Re: K083770
Trade/Device Name: Peristeen Anal Irrigation (PAI) System
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: October 14, 2009
Received: October 15, 2009

Dear Ms. Colley:

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

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K083770

Device Name: Peristeen Anal Irrigation (PAI) System

Indications for Use:

The Peristeen Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083770