

K103254  
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JAN 31 2011

### 3. 510(K) SUMMARY

**510(K) Owner's Name:** Coloplast A/S

**Address:** Hortedam 1  
3050 Humlebaek, Denmark  
Establishment Registration: 9610694  
Owner/Operator: 8010144

**Phone/Fax/Email:** Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
email: usb@coloplast.com

**Name of Contact Person:** Brian Schmidt  
Regulatory Affairs Manager

**Address/Contact:** 1601 West River Road  
Minneapolis, MN 55411

**Date Prepared:** November 2, 2010

**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 the Peristeen™ Anal Irrigation System cleared on November 23, 2009 under premarket notification 510(k) number K083770.

**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 does not contain natural rubber latex components.

**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 Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult 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 (expanded indications for use) is substantially equivalent to the Peristeen™ Anal Irrigation System.

**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 predicate, as well as acceptable results from functional performance and biocompatibility testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Coloplast A/S  
c/o Mr. Brian Schmidt  
Regulatory Affairs Manager  
Coloplast Manufacturing US, LLC  
1601 West River Road North  
MINNEAPOLIS MN 55411

JAN 3 1 2011

Re: K103254  
Trade/Device Name: Peristeen™ Anal Irrigation System  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Codes: KNT and FCE  
Dated: November 2, 2010  
Received: November 3, 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. 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.

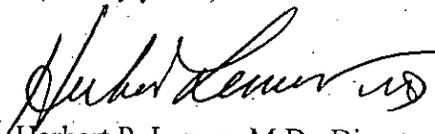
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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 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,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological 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): K103254

Device Name: Peristeen™ Anal Irrigation 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 Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use  (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, Gastro-Renal, and  
Urological Devices  
510(k) Number K103254