K121833
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4 510(k) Summary

510(k) Owner/SUBMITTER	Coloplast A/S Holtedam 1 3050 Humlebaek - Denmark
CONTACT PERSON	Tim Crabtree Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA Telephone:
DATE PREPARED	21 June 2012
CLASSIFICATION	Ostomy irrigator 876.5895 Class II
COMMON NAME	Irrigator, ostomy
PROPRIETARY NAME	Irrigation Set
PREDICATE DEVICE	K840268
DEVICE DESCRIPTION	The Irrigation Set is a Class II device, consisting of a single-use sleeve; a water bag (500-2000 ml) to hold water, a regulator where the paddle wheel that is integrated in the regulator gives visual assurance that water is entering the colon, a tube with a cone-shaped tip, a press plate and belt which are reusable devices. The Irrigation Set is provided with a nylon storage case.
INDICATIONS	The Irrigation Set is indicated for people with a stoma who want to irrigate. Irrigation Set has the same indications as the predicate device.
TESTING	The Irrigation Set water bag has been subjected to biocompatibility and mechanical testing and is substantially equivalent to the predicate Irrigation Set (K840268).
TECHNOLOGICAL CHARACTERISTICS	The Irrigation Set has the same intended use, general design, and fundamental scientific technology as the predicate Irrigation Set.
SUMMARY OF THE NONCLINICAL TESTS SUBMITTED	In vitro (bench) tests; accuracy of volume indicator, freedom from leakage, flow controller, hanging strength, biocompatibility.
SUMMARY OF CLINICAL TESTS SUBMITTED (AS APPLICABLE)	Not applicable
CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS	Substantial equivalence of the Irrigation Set is supported by a comparison of the design and intended use compared to the predicate, 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
% Mr. Tim Crabtree
Regulatory Affairs Manager
Coloplast Corp.
1601 West River Road North
MINNEAPOLIS MN 55411

JUL 16 2012

Re: K121833
Trade/Device Name: Irrigation Set
Regulation Number: 21 CFR§ 876.5895
Regulation Name: Ostomy irrigator
Regulatory Class: II
Product Code: EXD
Dated: June 21, 2012
Received: June 22, 2012

Dear Mr. Crabtree:

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

3 Statement of Indications for Use

Indications for Use

510(k) Number (if known): K121833

Device Name: Irrigation Set

Indications for Use:

The Irrigation Set is indicated for people with a stoma who want to irrigate.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (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 K121833