CONMED CORPORATION

510(k) Summary

JUL 14 2005

Submitter's Name: ConMed Corporation
Address: 525 French Road
Utica, New York 13502

Phone: 315-797-8375
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Contact Person: Ira Duesler
Director, RA/QA
Phone: 315-624-3072
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Date Summary Prepared: April 18, 2005

Name of Device: Irrigation Nozzle

Common or Usual Name: Colonic Irrigation System
Classification Name: Colonic Irrigation System

Predicate Devices: Jimmy John III Rectal Nozzle
Colon Therapeutics
510(k) Premarket Notification K973256
Approved September 29, 1997

GC Irrigator
Gentle Colonics, Inc.
510(k) Premarket Notification K980868
Approved August 6, 1998

Description of the Device:

The device is sterile, for single-use and is intended for use as an accessory with colonic irrigation systems in commercial distribution and acts as a nozzle when inserted into a patient's rectum to direct water into and cleanse the lower colon when medically indicated, such as before radiological or endoscopic examination. The nozzle is designed as a one-piece, injection molded plastic handpiece having a slight curvature at the end intended for insertion into the rectum. At the opposite end the device has a barbed fitting for attachment to the tubing from the colonic irrigation system. Several tip configurations are made available to provide options for the clinician.

Intended Use of Device:

The device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

Summary of the technological characteristics of device compared to predicate device:

The Irrigation Nozzle is substantially equivalent in every way to the Jimmy John III Rectal Nozzle and the GC Irrigator. All devices are for use for colon irrigation, used for similar populations, constructed of like or similar materials, manufactured similarly, and of a similar design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

Mr. Ira Duesler
Director, RA/QA
ConMed® Corporation
525 French Road
UTICA NY 13502

Re: K050992
Trade/Device Name: ConMed Irrigation Nozzle
Regulation Number: 21 CFR §876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: KPL
Dated: May 17, 2005
Received: May 19, 2005

Dear Mr. Duesler:

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 (Premarket Approval), 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 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" (21 CFR 807.97). 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) 443-6597 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

510(k) Number (if known): K050992

Device Name: ConMed Irrigation Nozzle

Indications For Use:

The ConMed Irrigation Nozzle is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

(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 ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050992