K123864
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Hollister

APR 17 2013

510(k) Summary

510(k) Owner:
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Submitted By:
Chris Stukel
Hollister Incorporated
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Libertyville, IL 60048
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Date Summary Prepared: December, 7, 2012

Device Name:

Classification Name - Gastrointestinal tube and accessories
21 CFR 876.5980-KNT
Common/Usual Name - Rectal Catheter
Proprietary Name - InstaFlo Bowel Catheter System Kit

Predicate Device:

Modifications are being made to the following predicate device:

Product	510(k)
InstaFlo Bowel Catheter System Kit	K100273

Device Description:

The InstaFlo Bowel Catheter System Kit contains two main parts: the catheter (made with odor barrier film) and the collection bag. The insertion end of the catheter contains a retention cuff and the other end of the catheter has a twist lock fitting to attach the collection bag. The retention cuff leads to a drain tube that allows stool to drain directly from the rectum into the bag. There are two catheter connectors attached to the catheter. The Blue connector is used to inflate and deflate the retention cuff. The Clear connector is used only to irrigate the device when needed.

Intended Use:

A bowel catheter system kit with odor barrier properties for diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.

Technological Characteristics: The table below summarizes the technological characteristics of the device as compared to the predicate devices.

Characteristics	InstaFlo Bowel Catheter System Kit (K100273)	InstaFlo Bowel Catheter System Kit MODIFIED DEVICE
Intended Use	For diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.	A bowel catheter system kit with odor barrier properties for diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.
Condition of Use	Single Use	
Kit Contents	• (1) Catheter • (1) 60cc Syringe • (1) Collection Bag • (1) Instructions for Use • (1) Quick Reference Insertion Guide	• (1) Odor Barrier Catheter • (1) 60cc Syringe • (1) Disposable Collection Bag with Filter • (1) Instructions for Use • (1) Quick Reference Insertion Guide
Catheter Material	Silicone	Thermoplastic
Catheter Odor Barrier Properties	No	Yes
Closed Waste Bag	Approximate Volume- 2000 mL Side catheter connector port No Filter	Approximate Volume- 2500 mL Top catheter connector port Filter

Performance Testing Conclusions:

Non-clinical testing of the proposed device for functional and structural parameters has been completed.

Biocompatibility testing was performed based on the United States Food and Drug Administration Office of Device Evaluation General program Memorandum #G95-1 and ISO 10993 biocompatibility testing standards. Results indicate compliance to the standard.

Odor testing was performed compared to the predicate to verify the odor barrier capabilities which the test results confirmed.

Connections and joints affected by the change in tubing were tested for bond strength and leakage to verify no impact to product design. Acceptable results were obtained, thereby demonstrating substantial equivalence.

In conclusion, based on the above information, the proposed device has been shown to be as safe and effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 17, 2013

Hollister Incorporated
% Ms. Chris Stukel
Sr. Global Regulatory Affairs Specialist
2000 Hollister Drive
LIBERTYVILLE, IL 60048

Re: K123804
Trade/Device Name: InstaFlo Bowel Catheter System Kit
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 5, 2013
Received: April 10, 2013

Dear Ms. Stukel:

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

Indications for Use

510(k) Number (if known): K123804

Device Name: InstaFlo Bowel Catheter System Kit

Indications for Use:

A bowel catheter system kit with odor barrier properties for diversion of liquid or semi-liquid stool to facilitate the collection of fecal matter in patients with little or no bowel control.

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)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123804