K083153

Hollister

FEB - 4 2009

510(k) Summary

Submitted By:

Chris Stukel
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60018
847-680-1000

Date Summary Prepared: October 23, 2008

Device Name: Classification Name- Gastrointestinal tube and accessories

Common/Usual Name-Rectal Irrigation Tube

Proprietary Name-ActiFlo™ Indwelling Catheter System Kit

Predicate Device: The ActiFlo™ Indwelling Catheter System Kit is equivalent to the following devices:

Product	510(k)
Indwelling Fecal Management System- Non-Sterile	K023344
Indwelling Fecal Management System (IFMS)	K012113

Device Description:The ActiFlo Indwelling Bowel Catheter System consists of a rectal catheter and accessories (waste collection bag, irrigation bag, skin barriers, syringe and lubricating jelly). The insertion end of the catheter contains a retention cuff and an intraluminal balloon, each with its own Luer connector used for inflation and deflation. A third connector provides a way to administer medications into the rectum and provides access for colonic irrigation. The ActiFlo Indwelling Bowel Catheter System allows stool to drain directly from the rectum into a closed or drainable collection bag.

Intended Use: The ActiFlo Indwelling Bowel Catheter System is intended for diversion of fecal matter to minimize external contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation and to administer enema/medications.

Technological Characteristics:

K083153

FUNCTION	ActiFlo™ Indwelling Bowel Catheter System Kit	Indwelling Fecal Management System-Non-Sterile (K023344)	Indwelling Fecal Management System (IFMS) K012113
Indications for Use	The ActiFlo Indwelling Bowel Catheter System is intended for diversion of fecal matter to minimize external contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation and to administer enema/medications.	Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enema/medications	Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enema/medications
Kit Contents	• (1) ActiFlo Catheter • (1) 60cc Syringe • (2) 5g Packet Water Soluble Lube • (1) Drainable Collection Bag or (2) Closed Collection Bags • (2) Skin Barriers • (1) Irrigation Bag • (1) Instructions for Use	• (1) IFMS Catheter • (1) 60cc Syringe • (1) 30cc Syringe • (2) 5g Packet Water Soluble Lube • (1) Instructions for Use	• (1) IFMS Catheter • (1) 60cc Syringe • (1) 30cc Syringe • (2) 5g Packet Water Soluble Lube • (1) Instructions for Use
Bowel Retention	External Balloon	Same	Same
Bowel Irrigation	Silicone funnel that is cath-tip syringe compatible; also comes with removable barbed connector for attachment to luer-tip syringe.	Silicone lumen with flared, capped port termination	Silicone lumen with flared, capped port termination
Port Access	Sampling / fluid administration	Same	Same
Drainage Flow Suspension	Intraluminal (ARV) balloon	Same	Same
Anti-Internal Migration	External silicone retention faceplate with 4 tape slots, 2 on each side	External silicone retention faceplate w/anchor tabs	External silicone retention faceplate w/anchor tabs
Flush / Stool Sampling	Same	Mid-line silicone access port compatible with catheter tip syringe	Mid-line silicone access port compatible with catheter tip syringe
Enema / Medication Administration	Silicone funnel that is cath-tip syringe compatible; also comes with removable barbed connector for attachment to luer-tip syringe.	Silicone lumen with flared, capped port termination	Silicone lumen with flared, capped port termination
Sterile	Non-Sterile	Non-Sterile	Sterile

Accessory Performance Testing Conclusions:

Biocompatibility testing was performed on the additional accessories based on the United States Food and Drug Administration Office of Device Evaluation General program Memorandum #G95-1 and ISO 10993 biocompatibility testing standards. Product evaluation supports acceptability of the added accessories for their intended clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

Ms. Christine L. Stukel
Sr. Global Regulatory Affairs Analyst
Hollister, Inc.
2000 Hollister Drive
LIBERTYVILLE IL 60048

Re: K083153
Trade/Device Name: ActiFlo™ Indwelling Bowel Catheter System Kit
Models 32004, -005, -006, and -007
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 26, 2009
Received: January 29, 2009

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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); 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

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

Indications for Use

510(k) Number (if known): K083153

Device Name: ActiFlo™ Indwelling Bowel Catheter System Kit

Indications for Use:

The ActiFlo Indwelling Bowel Catheter System is intended for diversion of fecal matter to minimize external contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation and to administer enema/medications.

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 K083153