510(k) Summary
Prepared July 15, 2013

JAN 2 4 2014

Sponsor:	Hospi Corporation 2384 Gehringer Drive Concord, CA 94520
Contact Person:	Igal Ladabaum
Telephone:	650-483-1035
Fax:	925-676-0151
Submission Date:	July 15, 2013
Device Name:	Macy Catheter
Common Name:	Rectal Catheter
Classification:	
Regulatory Class:	II
Review Category:	21 CFR Gastrointestinal Tube and Accessories (ref. 21 CFR 876.5980
Classification Panel:	Gastroenterology/Urology

A. Legally Marketed Predicate Devices
The Macy Catheter is substantially equivalent to the Indwelling Fecal Management System- Non-Sterile, (IFMS) manufactured by Bowel Management Systems (K023344).

B. Device Description
The Macy Catheter has been designed for comfort and safety by utilizing a flexible silicone body that enables administration of liquids/medications to the rectum. The device has two lumens, one for administering the liquids/medications and the other for inflation of the retention balloon. The catheter is inserted into the rectum and a small, soft retention balloon is inflated with water via the inflation valve. Liquids/medications are delivered via the medication valve, through the catheter, and into the rectum. The retention balloon can be easily deflated for removal of the catheter. The Macy Catheter remains in the rectum until expelled upon defecation (or removed for defecation if the patient prefers).

C. Intended Use
The Macy Catheter is intended to provide rectal access to administer liquids/medications.

D. Substantial Equivalence

The submission device is substantially equivalent to the Indwelling Fecal Management System- Non-Sterile (IFMS) manufactured by Bowel Management Systems (K023344).

Feature	**Predicate Device** Indwelling Fecal Management System-Non-Sterile (IFMS by Bowel Management Systems) K023344	**Subject Device** Macy Catheter
Indication for use	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 enemas/medication.	The Macy Catheter is intended to provide rectal access to administer liquids/medications.
Intended Users	Healthcare Professionals	Healthcare Professionals
Class	II	II
Regulation number Code	21CFR 876.5980 KNT	21CFR 876.5980 KNT
Catheter and lumen material	Silicone	Silicone, Compliant with ISO 10993
Retention Balloon	35-40ml water inflated silicone balloon, 2.08 inch outer diameter when inflated. Positioned adjacent to sphincter in distal rectum.	15 ml water inflated silicone balloon, 1.1 inch outer diameter when inflated. Positioned adjacent to sphincter in distal rectum.
Administration of Liquids/ Medications	Silicone lumen with flared caped port termination.	Silicone lumen with valved port for enteral/oral syringe.
Insertion Diameter	1.2 inches nominal	0.29 inches maximum
Fecal drainage lumen and stop-flow balloon	Yes	No
Safety features	Not specified in device labeling	Compliant with ISO 80369-1 minimizing risks of misconnection. Retention balloon, smaller than most formed stool, can be expelled with defecation; meets applicable test criteria of Standard Test Methods for Enteral Feeding devices with Retention Balloon.
Single use	Yes	Yes
Sterile	No	No
Length	64.5 Inches	20 Inches

E. Performance Data

Bench testing was conducted on the device to verify that it met design specification established under the Design Control Process with successful results. The performance

verification test results are provided in the submission under the section on Performance Data, Section 18. Biocompatibility testing was conducted in compliance with applicable parts of ISO 10993 as determined by ISO 10993 Part 1. Biocompatibility test reports are provided in the submission under the section on Biocompatibility Testing, Section 15.

The nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence include:

- Mechanical verification testing including ASTM F 2528-06 test methods (for example balloon and shaft size, balloon integrity and reliability via balloon volume maintenance and balloon burst volume tests, device tensile strength, lumen patency and flow rate, balloon and shaft mechanical properties).
- Packaging and shipping stress simulations
- Verification of design features intended to mitigate mistaken connections per ISO 80369-1.
- GLP test results for applicable biocompatibility testing. Test reports included are:
    - Cytotoxicity—medication valve as fabricated, leveraged catheter test article of identical fabrication but slightly different geometry and sterile.
    - Sensitization—medication valve as fabricated, leveraged catheter test article of identical fabrication but slightly different geometry and sterile.
    - Irritation—medication valve as fabricated, leveraged catheter test article of identical fabrication but slightly different geometry and sterile.
    - Systemic toxicity (acute)—catheter portion as fabricated.
    - Sub-chronic toxicity (sub-acute)—leveraged catheter test article of identical fabrication but slightly different geometry and sterile.
    - Genotoxicity—leveraged catheter test article of identical fabrication but slightly different geometry and sterile.
    - Muscle Implantation (test for local effects after implantation, 4 week)—test coupons cut from catheter as fabricated.

The results of the tests performed demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in Part A of this summary.

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

January 24, 2014

Hospi Corporation
% Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K133881
Trade/Device Name: Macy Catheter
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 8, 2014
Received: January 10, 2014

Dear Mark Job,

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,

Herbert P. Lerner -S

for
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): K133881

Device Name: Macy Catheter

Indications for Use: The Macy Catheter is intended to provide rectal access to administer liquids/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)

Herbert P. Lerner -S
2014.01.24 13:12:20 -05'00'