510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to 21 CFR807.92(a).

Submitter Information

Chad Coberly
Bowel Management Systems, LLC
1886 South 14th Street, Suite 6
Fernandina Beach, FL 32034
Phone: (904)261-2169
Fax: (904)261-2172

Date: September 27, 2002

807.92(a)(2)

Trade Name: Indwelling Fecal Management System- Non-Sterile
Common Name: Rectal Irrigation Tube
Classification Name(s): Tubes, Gastrointestinal
Classification Number: 78KNT

807.92(a)(3)

Predicate Device(s)

IFMS
Colo-Vage System
Virden Rectal Catheter
Leon's Fecal Tube
Bowel Management Systems, LLC
HDC Corp.
CR Bard
Leon's Fecal Tube Mfg.

Additional Substantial Equivalence Information is provided in the following substantial equivalence table.
510(k) Summary: Indwelling Fecal Management System
Bowel Management Systems, LLC

807.92(a)(5)

Intended Use(s)

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/medications.
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
<th>Steile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Specified</td>
<td>Not Specified</td>
<td>Administration</td>
<td>Sampling/Fluid</td>
<td>Port Access</td>
</tr>
<tr>
<td>Lumen with Hardened Silicone Lumen</td>
<td>Lumen with Hardened Silicone Lumen</td>
<td>Hardened Lumen</td>
<td>External Balloon</td>
<td>Silicone Lumen</td>
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<tr>
<td>No Information</td>
<td>No Information</td>
<td>Hardened Lumen</td>
<td>External Balloon</td>
<td>Silicone Lumen</td>
</tr>
<tr>
<td>External Ring</td>
<td>External Ring</td>
<td>Hardened Lumen</td>
<td>External Balloon</td>
<td>Silicone Lumen</td>
</tr>
<tr>
<td>Natural Rubber</td>
<td>Natural Rubber</td>
<td>Silicone</td>
<td>Materials</td>
<td>&quot;</td>
</tr>
</tbody>
</table>
Re: K023344  
Trade/Device Name: Indwelling Fecal Management System, Non-Sterile  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: 78 KNT  
Dated: September 27, 2002  
Received: October 7, 2002

Dear Mr. Coberly:

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 (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 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:

- 8xx.1xxx (301) 594-4591
- 876.2xxx, 3xxx, 4xxx, 5xxx (301) 594-4616
- 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx (301) 594-4616
- 892.2xxx, 3xxx, 4xxx, 5xxx (301) 594-4654
- Other (301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

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): K023344

Device Name: indwelling Fecal Management System, Bowel Management Systems, LLC

Indications 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)