June 1, 2018

Applied Medical Technology, Inc.
Joshua Meinke
Quality / Regulatory Affairs Supervisor
8006 Katherine Boulevard
Brecksville, OH 44141

Re: K180026
Trade/Device Name: Bowel Management Device and Irrigation Set
Regulation Number: 21 CFR § 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, EXD, PIF
Dated: April 23, 2018
Received: April 26, 2018

Dear Joshua Meinke:

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. 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/tray. 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -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
510(k) Number (if known)
K180026

Device Name
Bowel Management Device and Irrigation Set

Indications for Use (Describe)
The Bowel Management Device is intended to instill fluids through a stoma into the colon to promote evacuation of the contents of the lower bowel through the anus and is intended to be an aid in the management of fecal incontinence. The catheter is placed and maintained in a percutaneously prepared opening, such as a cecostomy or appendicostomy. The Bowel Management Device is intended to be used in children and adults.

The Bowel Management Irrigation Set is intended to allow connection between a compatible bowel management device and the delivery tubing of an irrigation/enema bag system.

Type of Use (Select one or both, as applicable)
- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Bowel Management Device and Irrigation Set

Date Prepared: May 31, 2018

Submitter: Applied Medical Technology, Inc.
8006 Katherine Boulevard
Brecksville, OH 44141
Phone: 440-717-4000
Fax: 440-717-4200
Contact Person: Joshua Meinke – Quality / Regulatory Affairs Supervisor
Email: Joshua.meinke@appliedmedical.net

Device Information:
Trade/Device Name: Bowel Management Device and Irrigation Set
Common Name: Gastrointestinal Tube
Classification Name: 21 CFR 876.5980: Gastrointestinal tube and accessories;
21 CFR 876.5895: Ostomy irrigator.
Product Code: KNT, EXD, PIF
Regulatory Class: II
Review Panel: Gastroenterology and Urology

Predicate Device:
Primary Predicate: Cook Chait Cecostomy Catheter (K982500)
Reference Device: AMT Low Profile Balloon Feeding Device (K161413)

Intended Use:
The Bowel Management Device is intended to instill fluids through a stoma into the colon to promote evacuation of the contents of the lower bowel through the anus and is intended to be an aid in the management of fecal incontinence. The catheter is placed and maintained in a percutaneously prepared opening, such as a cecostomy or appendicostomy. The Bowel Management Device is intended to be used in children and adults.

The Bowel Management Irrigation Set is intended to allow connection between a compatible bowel management device and the delivery tubing of an irrigation/enema bag system.
### Device Description:

The Bowel Management Device is an indwelling low profile catheter used to promote evacuation of the lower bowel through antegrade colonic flushing. It consists of an internal retention balloon and a flexible external bolster with a balloon fill-valve, interlock irrigation port, and safety plug. The catheter is inserted through the stoma and into the colon and is secured by the internal retention balloon when inflated. The Bowel Management Irrigation Set has a connector on one end that connects to the interlock on the catheter and an adapter on the other end to connect to the irrigation/enema delivery system. Fluids can then be instilled directly into the colon through the catheter.

### Technological Characteristics:

Antegrade colonic irrigation is the technological principle for both the subject and predicate device. It is based on the use of a stoma to instill fluids into the colon to evacuate the contents of the lower bowel through the anus. At a high level, the subject and predicate devices are based on the following same technological elements:

- Catheter tubing – to instill fluids into the colon
- External and internal bolster – to secure the device to the abdominal wall and prevent inward or outward migration of the device
- Plug on external bolster – to prevent leakage
- Introducer/stiffener – to facilitate placement of the device
- Irrigation set/access adapter – connects the catheter to the delivery system

The following technological differences exist between the subject and predicate device:

- The subject device is made of a soft, flexible silicone, while the predicate is made of urethane/polyurethane
- The subject device uses a balloon as the internal bolster instead of the catheter coiling like the predicate
- The subject device features one central outlet instead of having three side ports like the predicate device
- The subject device comes in various sizes to accommodate different stoma diameters and lengths and the predicate device is available in three adjustable sizes
- The subject device has an anti-reflux valve
- The subject device has an irrigation set that rotates to lock into place
- The subject device has an ENFit connector option for the irrigation set
- The subject device is MR conditional

### Biocompatibility Testing:

The Bowel Management Tube in its final finished form is identical to the Low Profile Balloon Feeding Device (K161413) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (eg. plasticizers, fillers, additives, cleaning agents, and mold release agents), so no additional testing was required for this submission.
AMT conducted various performance tests on the components contained within the Bowel Management Device. Testing found that all components and materials met or exceeded design specifications established by AMT.

In addition to testing included in K161413, bench tests have been carried out on to compare performance to the primary predicate. The additional tests carried out included:

- Strap Tensile Testing
- Tube Tensile Testing
- Minimum Overmold Bond Strength
- Stoma Pullout
- 2 Minute Leak Test
- Flow Rate Test
- Testing per ASTM F2528-06:
  - Balloon Integrity in Simulated Gastric Fluid
  - Balloon volume maintenance
  - Balloon size and shaft size
  - Balloon concentricity
  - Balloon integrity
- Testing per 80369-3:
  - Fluid leakage
  - Stress cracking
  - Resistance to separation from axial load
  - Resistance to separation from unscrewing
  - Resistance to overriding
  - Disconnection by unscrewing

The Bowel Management Devices meet all the acceptance criteria and performed comparable to or better than the primary predicate.

The Bowel Management Device can be found substantially equivalent to the predicate device cleared under K982500 in intended use, performance, and principles of operation. The AMT Bowel Management Device is also identical to the LPBFD cleared in K161413, so the technological characteristics do not raise different questions of safety and effectiveness.