June 6, 2017

Xeridiem Medical Devices
Steve Murray
Regulatory Affairs Specialist
4700 S. Overland Dr.
Tucson, Arizona 85714

Re: K171347
Trade/Device Name: Bi-Funnel and Tri-Funnel Gastrostomy Feeding Tubes with ENFit® connector, Entuit Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF
Dated: May 5, 2017
Received: May 8, 2017

Dear Steve Murray:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

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
4.0 Indications for Use Statement

4.1 Bi-Funnel/Tri-Funnel Gastrostomy Feeding Tubes with ENFit® connector

The Bi-Funnel and Tri-Funnel Gastrostomy Feeding Tubes with ENFit® connector are indicated for placement in adult populations that require enteral feeding, medication administration or gastric decompression through an established gastrointestinal stoma tract.
4.2 Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection

**Indications for Use**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

<table>
<thead>
<tr>
<th>510(k) Number (if known)</th>
<th>K171347</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection</td>
</tr>
</tbody>
</table>

The Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection is intended to provide gastric access for enteral feeding, medication administration and decompression through an established gastrointestinal stoma tract.

The Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection is indicated for use in percutaneous placement of an enteral feeding tube in adult and pediatric patients that require enteral feeding, medication administration or decompression through an established gastrointestinal stoma tract.

**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.*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3681 (8/14) Page 1 of 1

(End of Section)
5.0 510(k) SUMMARY

5.1 General Information

Date Prepared: May 4, 2017
510(k) Submitter: Xeridiem Medical Devices
4700 S. Overland Dr.
Tucson, AZ 85714

Contact Person: Steve Murray, Regulatory Affairs Specialist
(520) 882-77694 ext. 178
smurray@xeridiem.com

5.2 Device Information

5.2.1 Bundled Device 1

Trade Name: Bi-Funnel Gastrostomy Feeding Tube with ENFit® connector and Tri-Funnel Gastrostomy Feeding Tube with ENFit® connector
Common Name: Gastrostomy Feeding Tube
Classification Name: Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code PIF)
Classification Panel: Gastroenterology/Urology

5.2.2 Bundled Device 2

Trade Name: Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection
Common Name: Gastrostomy Feeding Tube
Classification Name: Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code PIF)
Classification Panel: Gastroenterology/Urology

5.3 Predicate Device Information (Device Being Modified)

5.3.1 Bundled Device 1

Trade Name: Bi-Funnel Gastrostomy Feeding Tube and Tri-Funnel Gastrostomy Feeding Tube
Common Name: Balloon Gastrostomy Feeding Tube
5.3.2 Bundled Device 2

**Trade Name:** Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube  
**Common Name:** Gastrostomy Tube  
**Classification Name:** Gastrointestinal tube and accessories (21 CFR 876.5980, Product Code KNT)  
**Classification Panel:** Gastroenterology/Urology  
**510(k) Number:** K130611/A001

5.4 Device Description

5.4.1 Bi-Funnel Gastrostomy Feeding Tube with ENFit® connector and Tri-Funnel Gastrostomy Feeding Tube with ENFit® connector

The Gastrostomy Feeding Tube (G-tube) consists of two product versions (models): a Bi-Funnel G-Tube and a Tri-Funnel G-Tube. Each G-Tube version is offered in varying shaft French (FR) sizes and balloon sizes. Both versions are offered in the same functional length. The overall difference between the Bi-Funnel and Tri-Funnel G-tubes is that the Tri-Funnel G-Tube allows for simultaneous delivery of feeding solutions and medications while the Bi-Funnel G-Tube allows for delivery of either feeding solutions or medications at a time.

The table below summarizes the device offerings for the Bi-Funnel and Tri-Funnel G-Tubes.

<table>
<thead>
<tr>
<th>Model P/N</th>
<th>Device Description</th>
<th>French Size Offerings (FR)</th>
<th>Balloon Recommended Fill Volume (mL)</th>
<th>Functional Length (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>70-0047</td>
<td>Bi-Funnel Gastrostomy Feeding Tube</td>
<td>12</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>18</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70-0048</td>
<td>Tri-Funnel Gastrostomy Feeding Tube</td>
<td>12</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>16</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Both Bi-Funnel and Tri-Funnel G-Tubes consist of a silicone funnel, shaft, adjustable external bolster and balloon. The funnel for the Bi-Funnel G-Tube has two ports: one port houses the balloon inflation valve which allows for balloon inflation and deflation, and the other port houses the male ENFit connector which allows for delivery of feeding solutions and medication. The funnel for the Tri-Funnel G-Tube has three ports: one port houses the balloon inflation valve, the center port houses the male ENFit connector which allows for delivery of feeding solutions, and the last (side) port houses another male ENFit connector which allows for delivery of medications. Attached to the ENFit connectors are a tether and a cap. The cap is intended to cover the ENFit connector when the device is not in use and the tether is intended to secure the cap to the connector when the device is in use. The same ENFit connector, tether and cap components are used for both Bi-Funnel and Tri-Funnel G-Tubes. The remaining components (shaft, adjustable bolster and balloon) are commonly shared for the Bi-Funnel and Tri-Funnel G-Tubes and are identical in both versions.

5.4.2 **Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection**

The Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection is constructed primarily of silicone. The device consists of a tri-port funnel which is overmolded onto a previously extruded bi-lumen shaft. A retention bolster is molded separately and placed over the shaft. At the proximal end, a silicone balloon is bonded to the shaft using silicone RTV. The tip of the shaft is filled with radiopaque barium RTV. In use, the balloon end of the catheter is inserted through a gastrointestinal stoma tract and into the stomach lumen. The balloon is then inflated to the rated volume using sterile or distilled water and the bolster adjusted down to the skin to secure the device in place. The table below summarizes the device offerings for the Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection.

<table>
<thead>
<tr>
<th>Model P/N</th>
<th>Device Description</th>
<th>French Size Offerings (FR)</th>
<th>Balloon Recommended Fill Volume (mL)</th>
<th>Functional Length (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>18</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The table above summarizes the device offerings for the Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection.
The funnel has three ports. One port contains the inflation valve and used for inflation of the balloon. The center port houses the male ENFit connector which allows for the delivery of feeding solutions. The third (side) port houses another male ENFit connector which allows for delivery of medications. Attached to the ENFit connectors are a tether and a cap. The cap is intended to cover the ENFit connector when the device is not in use and the tether is intended to secure the cap to the connector when the device is in use. The funnel configuration and ENFit connectors/caps are identical to the Tri-Funnel Gastrostomy Feeding Tube with ENFit connector discussed in 5.4.1 above.

5.5 Intended Use/Indications for Use

5.5.1 Bi-Funnel Gastrostomy Feeding Tube with ENFit® connector and Tri-Funnel Gastrostomy Feeding Tube with ENFit® connector

The Bi-Funnel and Tri-Funnel Gastrostomy Feeding Tubes with ENFit® connector are indicated for placement in adult populations that require enteral feeding, medication administration or gastric decompression through an established gastrointestinal stoma tract.

5.5.2 Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection

The Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection is intended to provide gastric access for enteral feeding, medication administration and decompression through an established gastrointestinal stoma tract.

The Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection is indicated for use in percutaneous placement of an enteral feeding tube in adult and pediatric patients that require enteral feeding, medication
administration or decompression through an established gastrointestinal stoma tract.

5.6 Technological Characteristics – Limited Device Modification

The device modification for both devices bundled in this premarket notification is changing the ENFit connector and cap material from ABS LG HF-380 to Nylon Vydyne 21X1. Otherwise, each device and its predicate is identically the same. There is no other change in technological characteristics and no change in intended use or indications for use. The extent of the material change is summarized in the table below.

<table>
<thead>
<tr>
<th>Device</th>
<th>Material Description</th>
<th>Proposed</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bi-Funnel and Tri-Funnel Gastrostomy Feeding Tubes with ENFit® connector</td>
<td>Nylon Vydyne 21X1 (MEVOPUR Violet AB4M665085 colorant)</td>
<td>ABS LG HF-380 (MEVOPUR Violet SB4M664930 colorant)</td>
<td></td>
</tr>
<tr>
<td>Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection</td>
<td>Nylon Vydyne 21X1</td>
<td>ABS LG HF-380</td>
<td></td>
</tr>
</tbody>
</table>

5.6 Compliance with Design Controls

Substantial equivalence of the proposed devices with the predicate devices are by compliance to the required design control activities for the device modification. These activities are summarized in the table below.

<table>
<thead>
<tr>
<th>Design Control Requirement</th>
<th>Design Control Activities</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design and Development Planning</td>
<td>Design and Development Plan – outline scope of project and major milestones, including risk management plan and analysis</td>
<td>Completed</td>
</tr>
<tr>
<td>Design Input</td>
<td>Traceability Matrix update – add new design inputs for ENFit connector robustness requirement under high torque and certain chemical exposure conditions</td>
<td>Completed</td>
</tr>
<tr>
<td>Design Output</td>
<td>Traceability Matrix update – specify design outputs for the added design inputs; update risk analysis (user and design FMEAs) appropriately to address the change</td>
<td>Completed</td>
</tr>
<tr>
<td>Design Review</td>
<td>Design reviews conducted for key milestones such as design inputs, design outputs, design verification completion, etc.</td>
<td>Completed</td>
</tr>
<tr>
<td>Design Verification</td>
<td>Documented in Verification and Validation Plan, summarized in Table 12.2</td>
<td>Completed</td>
</tr>
</tbody>
</table>
As summarized in the table above, required design controls activities were completed, including passing any required design verification activities.

5.6 **Substantial Equivalence Conclusion**

Based on successful completion of the required design control activities for the device modification that is the subject of this Special 510(k) premarket notification, it may be concluded that the following modified devices are substantially equivalent to their respective predicate devices:

- Bi-Funnel Gastrostomy Feeding Tube with ENFit® connector and
- Tri-Funnel Gastrostomy Feeding Tube with ENFit® connector
- Entuit® Gastrostomy BR Balloon Retention Feeding Tube with ENFit® Connection

*(End of Section)*