October 18, 2018

Xeridiem Medical Devices, A Spectrum Plastics Group Company
Steve Murray
Regulatory Affairs Specialist
4700 S. Overland Drive
Tucson, AZ 85714

Re: K180708
Trade/Device Name: Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube, Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube with ENFit Connection, Entuit LP Patient Care Kit, Entuit LP Patient Care Kit with ENFit Connection, PromaX Low Profile Gastrostomy Feeding Tube Kit with ENFit, PromaX LP Patient Care Kit with ENFit
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF, KNT
Dated: September 14, 2018
Received: September 17, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180708

Device Name
Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube
Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube with ENFit Connection

Indications for Use *(Describe)*
The feeding tube 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)*

☒ 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180708

Device Name
Entuit LP Patient Care Kit

Indications for Use *(Describe)*
The Entuit LP Patient Care Kit is indicated for use in adult and pediatric patients that require enteral feeding, medication administration or decompression through an Entuit LP Gastrostomy BR Balloon Retention Feeding Tube.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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See PRA Statement below.

510(k) Number *(if known)*
K180708

Device Name
Entuit LP Patient Care Kit with ENFit Connection

Indications for Use *(Describe)*
The Entuit LP Patient Care Kit with ENFit Connection is indicated for use in adult and pediatric patients that require enteral feeding, medication administration or decompression through an Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180708

Device Name
PromaX Low Profile Gastrostomy Feeding Tube Kit with ENFit

Indications for Use *(Describe)*
The feeding tube 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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180708

Device Name
PromaX LP Patient Care Kit with ENFit

Indications for Use *(Describe)*
The PromaX LP Patient Care Kit with ENFit is indicated for use in adult and pediatric patients that require enteral feeding, medication administration, or decompression through a PromaX Low Profile Gastrostomy Feeding Tube.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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5.0 510(k) SUMMARY

5.1 Submitter Information

Date Prepared: October 16, 2018

510(k) Submitter: Xeridiem Medical Devices,
A Spectrum Plastics Group Company
4700 S. Overland Dr.
Tucson, AZ 85714

Contact Person: Steve Murray, Regulatory Affairs Specialist
(520) 882-7794 ext. 178
smurray@xeridiem.com

5.2 Device Information

Trade Name:

- Entuit® LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube
- Entuit® LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube with ENFit® Connection
- Entuit® LP Patient Care Kit
- Entuit® LP Patient Care Kit with ENFit® Connection
- PromaX™ Low Profile Gastrostomy Feeding Tube Kit with ENFit®
- PromaX™ LP Patient Care Kit with ENFit®

Common Name: Low Profile Gastrostomy Tube
Classification Name: Gastrointestinal tube and accessories
(21 CFR 876.5980, Product Codes PIF, KNT)
Classification Panel: Gastroenterology/Urology

5.3 Predicate Device Information

Trade Name: Entuit™ Thrive LP Balloon Retention Gastrostomy Feeding Tube
Common Name: Gastrostomy Tube
Classification Name: Gastrointestinal tube and accessories
(21 CFR 876.5980, Product Codes KNT)
510(k) Number: K130674

5.4 Reference Device Information

Trade Name: EndoVive™ 3s Low Profile Balloon Kit
EndoVive™ 3s Bolus Extension Sets*
EndoVive™ 3s Continuous Extension Sets*
EndoVive™ 3s Medication Extension Set
Common Name: Gastrostomy Tube
Classification Name: Gastrointestinal tube and accessories (21 CFR 876.5980, Product Codes PIF, PIO)
510(k) Number: K142297

*These accessories are the only part of the cleared device being used for reference considerations.

5.5 Device Description

The proposed devices are listed below in Table 5.5-1 and are described following the table.

Table 5.5-1 – Proposed Devices

Device Part Number	Device Brand Name	Hereafter Referred to As
50-0423	Entuit® LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube	Entuit LP G-Tube
50-0416	Entuit® LP Patient Care Kit with ENFit® Connection	Entuit Patient Care Kit (ENFit)
50-0393	Entuit® LP Patient Care Kit	Entuit Patient Care Kit (Legacy)
70-0061	Entuit® LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube with ENFit® Connection (Kit)	Entuit Low Profile Kit (ENFit)
70-0069	Entuit® LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube (Kit)	Entuit Low Profile Kit (Legacy)
50-0435	PromaX™ Low Profile Gastrostomy Feeding Tube	PromaX LP G-Tube
50-0436	PromaX™ LP Patient Care Kit with ENFit®	PromaX Patient Care Kit (ENFit)
70-0072	PromaX™ Low Profile Gastrostomy Feeding Tube Kit with ENFit®	PromaX Low Profile Kit (ENFit)

The Low Profile Gastrostomy Tube Family will be comprised of two different brands of low profile gastrostomy tube kits – the Entuit Low Profile Kits (ENFit and Legacy versions) and the PromaX Low Profile Kit (ENFit), There are several minor design differences between the Entuit and PromaX offerings, including: hub strap width, extension set valve connector stem height, ENFit connector grip surface, length of ENFit feeding and Y-port stem on continuous extension set, and cap/tether configuration of the extension set for PromaX.

The proposed low profile devices are constructed primarily of silicone and consists of a hub which is overmolded on to a previously extruded bi-lumen shaft. At the distal end, a silicone balloon is bonded to the shaft using a silicone RTV. The tip of the shaft is filled

with radiopaque barium RTV. The hub has two ports. The top (center) port contains a reflux valve assembly which is keyed to accept the extension set connectors. Leaks are prevented by the reflux valve assembly (with cross-slit valve design). The second port is the inflation port and contains the inflation valve.

In use, the balloon end of the catheter is inserted through a gastrointestinal stoma tract and into the stomach. The balloon is then inflated with sterile or distilled water (per the recommended volume for the specific device size) to secure the device in place. To confirm placement of the device in the stomach, fluoroscopic procedures are typically used since the catheter shaft tip has radiopaque barium stripe present.

Accessories for the proposed devices include two extension set configurations (bolus and continuous, each available in both ENFit-compatible version and non-ENFit compatible version due to ENFit market transition status), an inflation syringe, a feeding syringe (similarly available in both ENFit compatible and non-ENFit compatible versions), gauzes, and a stoma measuring device (for the Entuit offering) to facilitate device placement and use.

The proposed low profile devices are available in the configurations shown below in Table 5.5-2.

Table 5.5-2 – LP G-Tube Configurations (Length [cm] for Each FR Size)

Size	0.8	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0
12 FR	✓	✓	✓	✓	✓	✓	✓	✓		
14 FR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16 FR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18 FR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
20 FR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
22 FR			✓	✓	✓	✓	✓	✓	✓	✓
24 FR			✓	✓	✓	✓	✓	✓	✓	✓

The extension sets have a valve connector end that inserts into the LP G-Tube reflux valve. For ENFit Extension Sets, the opposite end has an ENFit-compatible connector complying with ISO 80369-3 (for prevention of misconnections with non-enteral feeding devices). The extension set can then connect to any ENFit-compatible enteral giving sets or ENFit-compatible syringes. For Legacy Extension Sets (for the Entuit offering), the opposite end has a connector that can accept connection from non-ENFit catheter tip syringes and giving sets.

The ISO 80369-3 standard for enteral feeding ENFit connections was released in its final form on July 1, 2016. Progression of healthcare facilities adopting enteral devices with ENFit connectors has been slow as reported by industry organizations such as GEDSA and ECRI. As a result, both ENFit Extension Sets and Legacy Extension Sets are being made available to meet short-term patient needs.

The PromaX Low Profile Kits will only be offered in an ENFit version, targeted at the long term full market transition to ENFit connections.

5.6 Indications for Use

5.6.1 Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube and Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube with ENFit Connection

The feeding tube 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.

5.6.2 Entuit LP Patient Care Kit with ENFit Connection

The Entuit LP Patient Care Kit with ENFit Connection is indicated for use in adult and pediatric patients that require enteral feeding, medication administration or decompression through an Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube.

5.6.3 Entuit LP Patient Care Kit

The Entuit LP Patient Care Kit is indicated for use in adult and pediatric patients that require enteral feeding, medication administration or decompression through an Entuit LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube.

5.6.4 PromaX Low Profile Gastrostomy Feeding Tube Kit with ENFit

The feeding tube 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.

5.6.5 PromaX LP Patient Care Kit with ENFit

The PromaX LP Patient Care Kit with ENFit is indicated for use in adult and pediatric patients that require enteral feeding, medication administration, or decompression through a PromaX Low Profile Gastrostomy Feeding Tube.

5.7 Technological Characteristics

The proposed devices, as shown in Table 5.7 below with specific similarities and differences, have the same or very similar technological characteristics as the predicate device. The intended uses of the proposed devices and predicate device are the same and there are no significant differences noted in the table below that would affect the performance of the proposed devices as compared to the predicate device. The

Reference Device is used as the comparison in situations where the predicate device does not have the identified characteristic for proper comparisons (see table 5.7a below).

Table 5.7 – Device Comparison Table (Predicate Device)

	PREDICATE DEVICE (K130674) Entuit™ Thrive LP Balloon Retention Gastrostomy Feeding Tube	**PROPOSED DEVICE 1** Entuit® LP Gastrostomy BR Balloon Retention Feeding Tube Kit (and with ENFit® Connection)	**PROPOSED DEVICE 2** PromaX™ Low Profile Gastrostomy Feeding Tube Kit with ENFit®
Indications for Use	The Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube is indicated in adult and pediatric populations for use in percutaneous placement of an enteral feeding tube for feeding and/or administration of medication in conjunction with an established GI stoma tract. The replacement tube may also be used for gastric decompression.	The Entuit® LP Gastrostomy BR Low Profile Balloon Retention Feeding Tube 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.	The PromaX™ Gastrostomy Feeding Tube 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.
User Population	Adult and Pediatric	Same as K130674	Same as K130674
Operating Principle	Device tip enters through the stoma tract and into the stomach, then the device is secured in place by inflating the retention balloon. Once secured in place, the appropriate extension set is connected to the device and it then serves as a channel for administering nutrients and medication into the stomach and for gastric decompression.	Same as K130674	Same as K130674
Single Patient Use	Yes	Same as K130674	Same as K130674
Sterile	Yes (ETO) for pouch-sealed low profile device	Same as K130674	Same as K130674
Shaft	Silicone 65D	Same as K130674	Same as K130674
Balloon	Silicone 24D	Same as K130674	Same as K130674
Balloon Inflation Rating	5 mL	12-16 FR tubing size: 5-7 mL 18-24 FR tubing size: 5-10 mL	12-16 FR tubing size: 5-7 mL 18-24 FR tubing size: 5-10 mL
Reflux Valve	Silicone dome valve	Silicone cross-slit valve	Silicone cross-slit valve
Radiopaque Marker	Barium sulfate	Same as K130674	Same as K130674
Balloon Inflation Valve	Thermoplastic housing with silicone valve	Same as K130674	Same as K130674
Inflation Valve Port	Port on Silicone 60D hub which houses inflation valve	Slightly smaller ID to facilitate improved manufacturability	Slightly smaller ID to facilitate improved manufacturability

	PREDICATE DEVICE (K130674) Entuit™ Thrive LP Balloon Retention Gastrostomy Feeding Tube	**PROPOSED DEVICE 1** Entuit® LP Gastrostomy BR Balloon Retention Feeding Tube Kit (and with ENFit® Connection)	**PROPOSED DEVICE 2** PromaX™ Low Profile Gastrostomy Feeding Tube Kit with ENFit®
Connectors (Extension Sets)	Valve Connector – ABS, straight (bolus) or right angle (continuous) Feeding Connector – PVC, non-ENFit	Valve Connector – Polycarbonate, straight (bolus) or right angle (continuous) Feeding Connector – Nylon (ENFit)* or PVC non-ENFit (Legacy); Legacy Continuous ES has added medication port adapter cap	Valve Connector – Polycarbonate, straight (bolus) or right angle (continuous) Feeding Connector – Nylon (ENFit)*
Pinch Clamps (Extension Sets)	Bolus ES – 6.8 mm OD polypropylene pinch clamp; Continuous ES – 5.0 mm OD polypropylene pinch clamp	Both Bolus and Continuous ES – print device warning information on pinch clamp instead of warning tag; Continuous ES – 3.0 mm OD polypropylene pinch clamp (no change to pinch clamp for Bolus ES)	Both Bolus and Continuous ES – print device warning information on pinch clamp instead of warning tag; Continuous ES – 3.0 mm OD polypropylene pinch clamp (no change to pinch clamp for Bolus ES)
Warning Tags	Yes – for "Not for IV Use" warning	No – see pinch clamp printing above instead	No – see pinch clamp printing above instead
Kit Contents	Inflation syringe, feeding syringe, gauze, Bolus Extension Set, Continuous Extension Set	Same as K130674	Same as K130674
Packaging System/ Materials	Tyvek Pouch, Polybag, IFU, Corrugate Case & Shipper	Same as K130674	Same as K130674

*The Reference Device is used here as a comparison, since the predicate device does not have this characteristic.

Table 5.7a – Device Comparison Table (Reference Device)

	REFERENCE DEVICE (K142297) EndoVive™ 3s Bolus and Continuous Extension Sets	**PROPOSED DEVICE 1** Entuit® LP Patient Care Kit and Entuit® LP Patient Care Kit with ENFit® Connection	**PROPOSED DEVICE 2** PromaX™ LP Patient Care Kit with ENFit®
Indications for Use (applicable to extension sets)	The EndoVive™ 3s Extension Set is indicated for the delivery of nutrition, hydration and/or medication into the stomach through a low profile balloon and also provides a mechanism for gastric decompression.	The Entuit® LP Patient Care Kit is indicated for use in adult and pediatric patients that require enteral feeding, medication administration or decompression through an Entuit® LP Gastrostomy BR Balloon Retention Feeding Tube.	The PromaX™ LP Patient Care Kit with ENFit® is indicated for use in adult and pediatric patients that require enteral feeding, medication administration, or decompression through a PromaX™ Low Profile Gastrostomy Feeding Tube.

	REFERENCE DEVICE (K142297) EndoVive™ 3s Bolus and Continuous Extension Sets	**PROPOSED DEVICE 1** Entuit® LP Patient Care Kit and Entuit® LP Patient Care Kit with ENFit® Connection	**PROPOSED DEVICE 2** PromaX™ LP Patient Care Kit with ENFit®
Connectors (Extension Sets)	Valve Connector – Polycarbonate, straight (bolus) or right angle (continuous) Feeding Connector – Nylon ENFit	Valve Connector – Polycarbonate, straight (bolus) or right angle (continuous) Feeding Connector – Nylon (ENFit) or PVC (Legacy)	Valve Connector – Polycarbonate, straight (bolus) or right angle (continuous) Feeding Connector – Nylon (ENFit)

As can be seen from the above table, the changes are limited in scope and many characteristics are unchanged from the predicate device. The limited differences are as follows:

- The indications for use, while slightly changed in wording, does specify the same intended use and therefore does support substantial equivalence;
- The balloon inflation volume rating change from a fixed value to a range does not change functionality nor use of the device but only provides flexibility in meeting individual patient needs for device retention;
- The new reflux valve design (cross-slit) performs the same function as the predicate device's reflux valve and is shown to be equivalent or better based on performance testing, including creating an effective seal to the extension set valve connector;
- The inflation valve port has a minor dimensional change for improved manufacturability;
- The extension connectors similarly perform the same function as those of the predicate but incorporates a material change for improved strength of the valve connector and ISO 80369-3 (ENFit) compliance for the feeding connector (latter for the ENFit version only on both Entuit and PromaX);
- The new pinch clamp for the Continuous Extension Set performs the same function as the predicate but enables improved pinch clamp performance;
- Certain warning information is simply transferred from a warning tag to printing on the extension set pinch clamp itself;
- Entuit legacy Continuous Extension Set has an added medication port adapter cap (instructions provided in related IFU);
- In addition, PromaX valve connector has minor aesthetic differences (compared to Entuit) for market differentiation, including a slightly shorter stem.

Any differences noted above do not raise new or different questions of safety or effectiveness as compared to the predicate device. The proposed devices are deemed substantially equivalent.

5.8 Performance Data

5.8.1 Non-Clinical Tests

Based on detailed analysis of the proposed devices as compared to the predicate device and considering previous testing on materials in not only the predicate device but also other devices cleared for Xeridiem Medical Devices, required Verification and Validation Testing was decided upon for the proposed devices. It was found that the proposed devices are in compliance with design and performance requirements according to ISO 80369-3:2016 *Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications* (for the ENFit-compatible devices), EN1615:2000 *Enteral feeding catheters and enteral giving sets for single use and their connectors: Design and testing*, and biocompatibility requirements assessed per ISO 10993-1:2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

The following testing was conducted to support substantial equivalence of the proposed devices:

Biocompatibility

- Based on ISO 10993-1:2009 assessment, confirming cytotoxicity testing was performed per ISO 10993-5:2009

Sterilization

- Based on sterilization adoption assessment, confirming EO residuals testing was performed per ISO 10993-7:2008

Performance Testing – Bench

- Resistance to device migration (hub or balloon)
- Enteral feeding devices (with a retention balloon) testing per ASTM F2528-06
- Tensile testing per EN1615:2000 and EN 1618:1997
- Leak testing per EN1615:2000 and EN 1618:1997
- Connector insertion/removal force testing per EN1615:2000 and EN 1618:1997
- Low profile device-valve connector torque testing
- Dimensional testing of ENFit connectors per ISO 80369-3
- Extension set pinch clamp testing (able to stop fluid flow)
- Testing for resistance to expected chemical exposure
- Distribution simulation testing
- Design validation testing per simulated use conditions, including blenderized diet

Results from all the above tests met the acceptance criteria for each test.

5.8.2 Animal Tests

Animal tests were not required to demonstrate the performance of the proposed devices. Product functionality has been adequately assessed by the non-clinical tests discussed in 5.7.1.

5.8.3 Clinical Tests

Clinical tests were not required to demonstrate the performance of the proposed devices. Product functionality has been adequately assessed by the non-clinical tests discussed in 5.7.3.

5.9 Conclusion

The conclusions drawn from the device comparison for technological characteristics and results of the non-clinical testing demonstrate that the proposed devices in the Low Profile Gastrostomy Tube Family are as safe, effective, and perform as well or better than the legally marketed predicate device identified in 5.3, and/or the legally marketed reference device identified in 5.4.

(End of Section)