October 6, 2023

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

Re: K232046
Trade/Device Name: Kangaroo Skin Level Balloon Gastrostomy Kit, Kangaroo Bolus Feed Set with ENFIT Connection, Kangaroo Continuous Feed Set with ENFIT Connection
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF
Dated: July 5, 2023
Received: July 10, 2023

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232046

Device Name
Kangaroo Skin Level Balloon Gastrostomy Kit
Kangaroo Bolus Feed Set with ENFIT Connection
Kangaroo Continuous Feed Set 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.

The Kangaroo Skin Level Gastrostomy Device Feed Set Kit with ENFit® Connection is indicated for use in adult and pediatric patients that require enteral feeding, medication administration, or decompression through a Kangaroo Skin Level Device.

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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5.0 510(k) SUMMARY

5.1 Submitter Information

Date Prepared: June 30, 2023
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
steven.murray@spectrumplastics.com

5.2 Device Information

Trade Name: Kangaroo™ Skin Level Balloon Gastrostomy Kit
Kangaroo™ Bolus Feed Set with ENFit® Connection
Kangaroo™ Continuous Feed Set with ENFit® Connection

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

5.3 Predicate Device Information

Trade Name: Entuit® LP Gastrostomy BR Balloon Retention
Feeding Tube Kit with ENFit® Connection
Common Name: Low Profile Gastrostomy Tube
Classification Name: Gastrointestinal tube and accessories
(21 CFR 876.5980, Product Code PIF)
510(k) Number: K180708

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

* Low profile device from the Low Profile Balloon Kit is the only part of the cleared device being used for reference considerations in technological characteristics.

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
50-0508	Kangaroo™ Skin Level Device	Kangaroo™ SLD
70-0079	Kangaroo™ Skin Level Balloon Gastrostomy Kit	Kangaroo™ SLD Kit
20-1724	Kangaroo™ 24" Continuous Feed Extension Set	Continuous ES
20-1725	Kangaroo™ 12" Bolus Feed Extension Set	Bolus ES
50-0509	Kangaroo™ Bolus Feed Set with ENFit® Connection (10 pack of Bolus Feed Set)	FSK – Bolus
50-0510	Kangaroo™ Continuous Feed Set with ENFit® Connection (10 pack of Continuous Feed Set)	FSK – Continuous

The Kangaroo™ Skin Level Balloon Gastrostomy Kit will be comprised of one Kangaroo™ Skin Level Device and one of each of the feed sets. The feed sets, continuous and bolus, are also available in Feed Set Kits packaged individually and then boxed as a 10-pack.

The Kangaroo™ SLD is constructed primarily of silicone and consists of a hub which is overmolded on to a previously extruded bi-lumen shaft. The tip of the shaft is filled with radiopaque barium RTV. At the distal end, a silicone subsumed tip balloon is reverse bonded to the shaft using a silicone RTV. This subsumed tip balloon accomplishes patient comfort by not exposing the tip of the shaft to the patient as well as being in line with the shaft. 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 Kangaroo™ SLD include two feed extension set configurations (ENFit bolus and continuous), an inflation syringe, a feeding syringe (ENFit), and gauzes.

The hub has two ports. The top (center) port contains a reflux valve assembly which is keyed to accept the feed set valve 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.

The device is available in the configurations per determined market needs shown below in Table 5.5-2.

Table 5.5-2 – Kangaroo™ SLD Configurations (Length [cm] for Each FR Size)

FR SIZE	LENGTH (CM)													
	0.8	1.0	1.2	1.5	1.7	2.0	2.3	2.5	2.7	3.0	3.5	4.0	4.5	5.0
12	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
20	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
22	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
24	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

The feed extension sets have a valve connector end that inserts into the Kangaroo™ SLD reflux valve. For these ENFit Feed 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. Finally, both the Kangaroo™ Skin Level Device and the Kangaroo™ Feed Sets are compatible with competitor devices currently on the market.

5.6 Indications for Use

5.6.1 Kangaroo™ Skin Level Balloon Gastrostomy Kit

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.

The Kangaroo™ Skin Level Gastrostomy Device Feed Set Kit with ENFit® Connection is indicated for use in adult and pediatric patients that require enteral feeding, medication administration, or decompression through a Kangaroo™ Skin Level Device.

5.6.2 Kangaroo™ Bolus Feed Set with ENFit® Connection and Kangaroo™ Continuous Feed Set with ENFit® Connection (10-Pack Kits)

The Kangaroo™ Skin Level Gastrostomy Device Feed Set Kit with ENFit® Connection is indicated for use in adult and pediatric patients that require enteral feeding, medication administration, or decompression through a Kangaroo™ Skin Level Device.

5.7 Technological Characteristics

The proposed device, 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 device 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 device as compared to the predicate device. The reference device is used as the comparison for certain balloon characteristics (see Table 5.7a below the main table).

Table 5.7 – Device Comparison Table (Predicate Device)

	PREDICATE DEVICE (K180708) Entuit® LP Gastrostomy BR Balloon Retention Feeding Tube Kit with ENFit® Connection	**PROPOSED DEVICE** Kangaroo™ Skin Level Device Kit with Feed Sets
FDA Class	Class II	Same as K180708
FDA Product Code	PIF (for ENFit-compatible)	Same as K180708
FDA Regulation	876.5980 – Tubes, gastrointestinal (and accessories)	Same as K180708
510(k) Number	K180708	TBD
Indications for Use	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.	Same as K180708
User Population	Adult and Pediatric	Same as K180708
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 K180708
Single Patient Use	Yes	Same as K180708

	PREDICATE DEVICE (K180708) Entuit® LP Gastrostomy BR Balloon Retention Feeding Tube Kit with ENFit® Connection	**PROPOSED DEVICE** Kangaroo™ Skin Level Device Kit with Feed Sets
Sterile	Yes (ETO) for pouch-sealed low profile device	Same as K180708
Shaft	Silicone 65D	Silicone 65D (same as K180708); adds four additional functional lengths: 1.2cm, 1.7cm, 2.3cm, 2.7cm
Balloon	Silicone 24D	Silicone 24D (with reverse bonding for subsumed device tip)*
Balloon Inflation Rating	12-16 FR tubing size: 5-7 mL 18-24 FR tubing size: 5-10 mL	12 FR tubing size: 4 mL* 14 FR tubing size: 4.5 mL* 16 FR tubing size: 5 mL* 18 FR tubing size: 6 mL* 20 FR tubing size: 7 mL* 22 FR tubing size: 8 mL* 24 FR tubing size: 10 mL*
Reflux Valve	Silicone cross-slit valve	Silicone cross-slit valve (with silicone back-up seal)
Radiopaque Marker	Barium sulfate	Same as K180708
Balloon Inflation Valve	Thermoplastic housing with silicone valve	Same as K180708
Inflation Valve Port	Port on Silicone 60D hub which houses inflation valve	Same as K180708
Connectors (Feed Extension Sets)	Valve Connector – Polycarbonate, straight (bolus) or right angle (continuous) Feeding Connector – Nylon (ENFit)	Same as K180708
Pinch Clamps (Feed Extension Sets)	Both Bolus and Continuous ES – print “Not for IV Use” symbol and “For Enteral Use Only” warning on pinch clamp; Bolus ES – 6.8 mm OD polypropylene pinch clamp Continuous ES – 3.0 mm OD polypropylene pinch clamp	Same as K180708
Low Profile Kit Contents	Inflation syringe, feeding syringe, gauze, Bolus Extension Set, Continuous Extension Set	Same as K180708
Replacement Feed Extension Kit Contents	1 each Bolus Extension Set and Continuous Extension Set	10 each Bolus Feed Extension Sets or 10 each Continuous Feed Extension Sets
Packaging System/ Materials	Tyvek Pouch (only with LPK), Polybag, IFU, Corrugate Case & Shipper	Same as K180708
Competitor Device Compatibility	No	Yes – for select competitor devices (competitor ES with Kangaroo SLD; competitor LP device with Kangaroo Feed Sets)

*The Reference Device comparison in Table 5.7a supports these balloon characteristics.

Table 5.7a – Device Comparison Table (Reference Device)

	REFERENCE DEVICE (K142297) EndoVive™ 3s Low Profile Balloon Kit	**PROPOSED DEVICE** Kangaroo™ Skin Level Device Kit with Feed Sets
Indications for Use (applicable to low profile device)	The EndoVive 3S Low Profile Balloon is indicated for use in adult and pediatric patients who require long term feeding, are unable to tolerate oral feeding, are at low risk for aspiration or require gastric decompression and/or medication delivery directly into the stomach.	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.
Balloon	Silicone 24D (with reverse bonding for subsumed device tip)	Same as K142297
Balloon Inflation Rating	12 FR tubing size: 4 mL 14 FR tubing size: 4.5 mL 16 FR tubing size: 5 mL 18 FR tubing size: 6 mL 20 FR tubing size: 7 mL 22 FR tubing size: 8 mL 24 FR tubing size: 10 mL	Same as K142297

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

- Addition of four additional functional lengths on the Skin Level Device (low profile gastrostomy tube) only offers additional options but does not impact functionality of the device;
- Balloon is reverse bonded to create a subsumed device tip for enhanced patient comfort while retaining equivalent performance in retention;
- The balloon inflation volume rating difference is due to the reverse bonded balloon process; the balloon is reversed and trimmed, resulting in less surface area of the balloon; the balloon is then positioned over the shaft, crating a subsumed tip when inflated; this process results in enhanced patient comfort but a decrease in inflation volume for most FR sizes; however, performance testing indicates retention requirements are met;
- The updated reflux valve design (cross-slit valve with silicone back-up seal) performs the same function as the predicate device's reflux valve and is shown to be equivalent or better based on performance testing;
- The change from providing replacement feed extension sets in a pack of 1 each bolus/continuous to 10-pack of either bolus or continuous simply provides

convenient options for replacing the type set a specific user needs and has no impact on safety or effectiveness;
- Compatibility of the Kangaroo™ devices with select competitor devices offers more flexibility to the end user and has been verified through performance testing.

Any differences noted above do not raise new or different questions of safety or effectiveness as compared to the predicate device. The proposed device is 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 (documented design equivalency analysis) and considering previous testing on materials in both the predicate and reference devices, it was determined what new Verification and Validation Testing was required for the proposed devices and what testing can be legitimately leveraged from the predicate and reference devices. Based on the combination of new and leveraged testing, it was found the proposed devices are in compliance with design and performance requirements according to ISO 80369-3:2016/AMD1:2019 *Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications*, EN1615:2000 *Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing* (with additional support from *ISO 20695:2020 Enteral feeding systems – design and testing*), and biocompatibility requirements per ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

The following testing was conducted on proposed devices or leveraged from the predicate device or reference device (leveraging based on design equivalency) to support substantial equivalence of the proposed devices:

Biocompatibility
- Per prior assessment consistent with ISO 10993-1:2018, confirming cytotoxicity, sensitization and irritation tests completed on predicate device and deemed applicable to proposed device per design equivalency assessment

Sterilization
- Based on sterilization adoption assessment and design equivalency assessment, EO residuals testing on predicate device deemed applicable to proposed device

Performance Testing – Bench (combined new and leveraged)
- Resistance to device migration (hub or balloon)
- Enteral feeding devices (with a retention balloon) testing per ASTM F2528-06(2014)

- Tensile testing per EN 1615:2000 and EN 1618:1997
- Leak testing per EN1615:2000, EN 1618:1997 and ISO 20695:2020
- Valve connector insertion/removal force testing per ISO 20695:2020
- Low profile device-valve connector torque testing
- Feed/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 5.8.1.

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 5.8.1.

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 Kangaroo™ device 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)