April 20, 2026

Luminoah
Edgar (Rawley) Rearick
Director of Quality
1 Morton Dr., Suite 100
Charlottesville, Virginia 22903

Re: K253558
Trade/Device Name: Luminoah FLOW™ Enteral Nutrition System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZH
Dated: March 20, 2026
Received: March 20, 2026

Dear Edgar (Rawley) Rearick:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253558

Please provide the device trade name(s).

Luminoah FLOW™ Enteral Nutrition System

Please provide your Indications for Use below.

The Luminoah Flow™ Enteral Nutrition System is intended for the delivery of supplemental nutrition and fluids to the gastrointestinal system including nutritional formula, fluids, and/or water. The system is intended for use by healthcare professionals (HCP) to laypersons.

The Luminoah Flow™ Enteral Nutrition System is indicated for use in individuals who are unable to obtain sufficient nutrition through eating and or swallowing. The system is indicated for use with the Luminoah Flow™ Administration Set and Luminoah branded accessories.

The Luminoah Flow™ System can be used by an adult layperson, caretaker, or healthcare professional, for both adult and pediatric patients, ages 2 years and older. This system is not intended for use with neonates.

The Luminoah Flow™ Enteral Nutrition System is intended for hospital and acute care settings, as well as for home health use. It is intended to be used in both stationary and ambulatory conditions.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary – K253558

Applicant / Manufacturer Name:	Luminoah 1 Morton Drive, Suite 100 Charlottesville, VA 22930
Corresponding Official:	Edgar (Rawley) Rearick Director of Quality Luminoah, Inc.
Telephone Number:	(540) 480-2074
Email:	rrearick@luminoah.com
Date prepared:	04/14/2026

DEVICE IDENTIFICATION

Trade Names:	Luminoah FLOW™ Enteral Nutrition System
Common Name:	Enteral Feeding Pump, Infusion Pump
Classification Name:	Infusion pump
Regulation Number:	21CFR 880.5725
Classification:	Class II
Product Code:	LZH

PREDICATE DEVICE

Trade Names:	Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal
510(K) Number:	K153074

LUMINOAH

DEVICE DESCRIPTION

The Luminoah FLOW™ Enteral Nutrition System consists of an enteral nutrition pump and disposable enteral nutrition sets, and Luminoah FLOW™ accessories to deliver formula via rotary peristaltic pumping to provide nutrition for those who do not have the ability to orally ingest food.

The Luminoah Flow™ Administration Set is intended for products with ENFit™ Male Connectors. Do not use with non-ENFit connectors. Do not use the device with small bore connectors from other healthcare applications. The Luminoah Flow has been validated for use with nasally inserted enteral feeding tubes (NG, ND, NJ) and extension sets of size 6 French or greater with up to 2 ports and with internal volumes up to 4.3 mL. It has not been validated with giving sets that include any additional in-line resistance.

INDICATIONS FOR USE

The Luminoah Flow™ Enteral Nutrition System is intended for the delivery of supplemental nutrition and fluids to the gastrointestinal system including nutritional formula, fluids, and/or water. The system is intended for use by healthcare professionals (HCP) to laypersons.

The Luminoah Flow™ Enteral Nutrition System is indicated for use in individuals who are unable to obtain sufficient nutrition through eating and or swallowing. The system is indicated for use with the Luminoah Flow™ Administration Set and Luminoah branded accessories.

The Luminoah Flow™ System can be used by an adult layperson, caretaker, or healthcare professional, for both adult and pediatric patients, ages 2 years and older. This system is not intended for use with neonates.

The Luminoah Flow™ Enteral Nutrition System is intended for hospital and acute care settings, as well as for home health use. It is intended to be used in both stationary and ambulatory conditions.

SUBSTANTIAL EQUIVALENCE COMPARISON

The Luminoah FLOW™ Enteral Nutrition System, comprised of the FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets, and FLOW™ Accessories is substantially equivalent for its intended use, use conditions and use environment compared to the currently marketed predicate Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal. The table below is a comparison of the subject and predicate device regarding substantial equivalence.

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Indications For Use	The Kangaroo™ Connect. Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets is intended to deliver nutritional formula to the gastrointestinal system of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates. The feeding pump and feeding sets are intended to be used in clinical or home care settings by users ranging from laypersons to physicians.	The Luminoah Flow™ Enteral Nutrition System is intended for the delivery of supplemental nutrition and fluids to the gastrointestinal system including nutritional formula, fluids, and/or water. The system is intended for use by healthcare professionals (HCP) to laypersons. The Luminoah Flow™ Enteral Nutrition System is indicated for use in individuals who are unable to obtain sufficient nutrition through eating and/or swallowing. The system is indicated for use with the Luminoah Flow™ Administration Set and Luminoah branded accessories. The Luminoah Flow™ System can be used by an adult layperson, caretaker, or healthcare professional for both adult and pediatric patients, ages 2 years and older. This system is not intended for use with neonates. The Luminoah Flow™ Enteral Nutrition System is intended for hospital and acute care settings as well as for home health use. It is intended to be used in both stationary and ambulatory conditions.	General purpose of the subject device, its function, indications for use, and use conditions are the same as predicate device. The FLOW Enteral Nutrition System is designed specifically for patients ages 2 years and older.
Sterility	Non-Sterile Feeding sets	Non-Sterile feeding sets	Same

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Technical Characteristics	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate. The connection to the patient enteral access device is an ENFit Connector compliant to ISO 80369-3.	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate. The connection to the patient enteral access device is an ENFit Connector compliant to ISO 80369-3.	Same
Design (pump)	The pump incorporates a menu controlled operating system which contains on board custom software designed to allow the user to set feed rates and volumes as well as other feeding options. The device incorporates ultrasonic sensors to detect the air and blockages in the feeding set.	The pump incorporates a menu controlled operating system which contains on board custom software designed to allow the user to set feed rates and volumes as well as other feeding options. The device incorporates an (1) optical sensor to detect the air in the tubing, and blockages in the feeding set are detected through motor monitoring of current and pulse width modulation.	Difference in design that does not introduce or raise concerns regarding the safe and effective use of the subject device.

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Design (feeding set)	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1000ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (14 inch) • Cassette containing pump interface module (peristaltic tubing) • Tubing from pump to patient connector (66 inches) • Patient connector (EnFit connector compliant to ISO 80369-3)	The pump set incorporates 2 basic segments: • Fluid reservoir(s) (250ml or 500ml) • Pump Head (inclusive of): - Spike Connector - Tubing from spike connector to patient connector (15 inches) - Pump head housing that attaches to FLOW pump - Patient connector (EnFit connector compliant to ISO 80369-3)	Different in design only – does not introduce or raise concerns regarding the safe and effective use of the subject device.
Graphic Display	Color TFT (320X240 pixels)	Color TFT 2.8” display	Same
Ingress Rating	IP26	IP24	Different in design only – does not introduce or raise concerns regarding the safe and effective use of the subject device.
Free Flow Mechanism	Anti-Free Flow Valve	Anti-Free Flow Mechanism (Vacuum)	Different in design only – does not introduce or raise concerns regarding the safe and effective use of the subject device.
Feed Capability	Yes	Yes	Same
Feed and Flush Capability	No	Yes	Different in design – FLOW includes added functionality to allow users to flush (or ‘rinse’) the administration sets between uses
Thick Formula Capability	No	No	Same

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Occlusion Detection (time), 1-50 mL/hr	Upstream: <=350 minutes	Upstream: <=180 minutes	Different in design – FLOW has a shorter detection threshold (time). Does not introduce or raise concerns regarding the safe and effective use of the subject device.
	Downstream: <= 95 minutes	Downstream: <= 95 minutes	Same
Occlusion Detection (time), >50 mL/hr	Upstream: <=9 minutes	Upstream: <=15 minutes	Different in design – FLOW has increased detection threshold (time). Does not introduce or raise concerns regarding the safe and effective use of the subject device.
	Downstream: <= 3 minutes	Downstream: <=15 minutes	Different in design – FLOW has increased detection threshold (time). Does not introduce or raise concerns regarding the safe and effective use of the subject device.
Accuracy	± 5% or 0.5 mL/hr, whichever is larger	± 5% or 0.5 mL/hr, whichever is larger	Same. The following factors may affect flow rate accuracy: ambient temperature, fluid temperature, pressure (e.g., head-height, backpressure, atmospheric pressure), fluid viscosity.
Delivery Rate Range	1 – 600mL/hr in 1 mL increments	1 – 600mL/hr in 1 mL increments	Same

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Dose Range	1 – 3000mL in 1 mL increments	1 – 500mL in 1 mL increments	Different in design only - The subject device has a narrower dose range, but the range remains within the predicate device range. Does not introduce or raise concerns regarding the safe and effective use of the subject device.
Power requirements	120V, 60Hz, 1Amp	120V, 60Hz, .35Amp	Different in design only – does not introduce or raise concerns regarding the safe and effective use of the subject device.
Auto prime	Yes	Yes	Same
Maximum Occlusion Pressure	20psi	20psi	Same
Size	3.9” x 6.1” x1.6”	2.6” x 5.2” x 1.75”	Different in design only – does not introduce or raise concerns regarding the safe and effective use of the subject device.
Weight	0.73lbs (0.33kg)	0.62lbs (0.28kg)	Different in design only – does not introduce or raise concerns regarding the safe and effective use of the subject device.
Pole Clamp Mountable	Yes	Yes	Same
Battery Type	Rechargeable Lithium Ion	Rechargeable Lithium Ion	Same
Battery Life	24hrs	≥24hrs	Same
Battery re-charge time	7hrs	~4.5hrs	Different by design – FLOW has a faster recharge time. Does not introduce or raise concerns regarding the safe and effective use of the subject device.

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Battery Operation Indicator	Yes	Yes	Same
Operating Temperature Range	5º - 40ºC (41º - 104ºF) @ 93% R.H. (non-condensing)	5º - 40ºC (41º - 104ºF) @ 90% R.H. (non-condensing)	Different - The subject device has a narrower humidity range, but the range remains within the predicate device range. does not introduce or raise concerns regarding the safe and effective use of the subject device
Storage Temperature Range	0º - 50ºC (32º - 122ºF) @ 93% R.H. (non-condensing)	0º - 50ºC (32º - 122ºF) @ 90% R.H. (non-condensing)	Different - The subject device has a narrower humidity range, but the range remains within the predicate device range. does not introduce or raise concerns regarding the safe and effective use of the subject device
Medical and Electrical Safety Standards	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-24 IEC 62304 IEC 62366	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-24 IEC 62304 IEC 62366	Same
Degree of Protection against electrical shock	Class 2 Type BF per IEC Standards	Class 2 Type BF per IEC Standards	Same
Power Adapter	Yes	Yes	Same

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Pump Control Alarms and Notifications	Alarms: System Error Feed Bag Empty Supply Tube Blocked Patient Tube Blocked Cassette Dislodged Cassette Error Rotor Stuck Dead Battery Notifications: Feeding Complete Feeding Incomplete Low Battery Pump Inactive	Alarms: Motor Stuck Incomplete Feed Low Battery Upstream Occlusion Downstream Occlusion Administration Set Error Dead Battery Air-in-Line Stuck Button Temperature Feed Interrupted System Error Notifications: Feeding Complete Hydration Complete End of Priming Sequence Insufficient Charge Feeding Paused Snoozed Alarm	Difference in design that does not introduce or raise concerns regarding the safe and effective use of the subject device
Timed Pause Feature	Displayed as KTO VOL delivered at maximum time interval	Not Included	Different – convenience feature not offered by Luminoah FLOW. Does not introduce or raise concerns regarding the safe and effective use of the subject device.

Characteristic	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets (Predicate Device)	Luminoah FLOW™ Enteral Nutrition System: FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ accessories (Subject Device)	Comparison to Predicate
Materials/Chemical composition	Polyvinyl chloride (PVC) • Feeding bags and caps • Tubing Silicone • Peristaltic tubing • Diaphragm valve Polycarbonate • Cassette body Copolyester • Patient connector ABS • Spike • Tube holder and Cap Strontium Ferrite / nylon • Set ID magnets	Nylon ● Pump Housing Impact Copolymer PP ● Administration Set Housing Silicone ● Administration Set Tubing PET/PE blend ● Nutrition Pouch ABS • Spike • Tube holder and Cap Neodymium Magnets • Back attachment magnets	Different – Subject device uses different materials that are supported by biocompatibility testing. Does not introduce or raise concerns regarding the safe and effective use of the subject device.
Service Life	5 years	1 year	Different by design – Difference in service life does not introduce or raise concerns regarding the safe and effective use of the subject device.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The primary difference between the predicate Kangaroo™ Connect Enteral Feeding Pump cleared under K153074 and the proposed Luminoah FLOW™ Enteral Nutrition System are the sensors used to monitor pump function. The sensing methodology in the FLOW system achieves equivalent monitoring of single faults related to blockage and air in line. Motor monitoring allows for an alternative method of occlusion detection while monitoring from the source of mechanical output / fluid delivery rather than an external sensor.

PERFORMANCE TESTING

A Safety Assurance Case (SAC) as recommended by the FDA guidance document, Infusion Pumps Total Product Life Cycle is provided for the Luminoah FLOW™ Enteral Nutrition System, including the FLOW™

Durable Pump, FLOW™ Administration Aet and Luminoah FLOW™ Accessories. The stated top-level claim of the SAC is:

> *The Luminoah FLOW™ Enteral Nutrition System*, comprised of the FLOW™ Enteral Feeding Pump, FLOW™ Administration Sets and FLOW™ Accessories *are acceptably safe for its intended use, within its environment of use, when being used by intended users, over the lifecycle of the product.*

The following specific evidence was included within the SAC to demonstrate that the subject device is verified and validated for its intended use, and to demonstrate substantial equivalence to the predicate device.

Software	Software verification and validation per FDA guidance for the *Content of Premarket Submissions for Device Software Functions* (June, 14, 2023) for Enhance Documentation level and FDA guidance document *Infusion pump total product life cycle* (December 2, 2014)
Electrical Safety	The electrical safety evaluation of the medical electrical equipment was performed per standards IEC60601-1 *Medical electrical equipment part1: General requirements for basic safety and essential performance*
EMC	The electromagnetic compatibility was evaluated to IEC 60601-1-2: *Medical electrical equipment- Part 2: General requirement for basic safety and essential performance - Collateral standard: electromagnetic compatibility - Requirements and tests* and per FDA guidance document *Electromagnetic Compatibility (EMC) of Medical Devices*.
Device Performance	The performance requirements of the device (including feeding sets) were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance “Infusion Pumps Total Product Life Cycle” including: • Performance testing • Reliability testing • Flow rate accuracy testing across all operating conditions (in accordance with AAMI TIR101:2021) • Alarm detection
Human Factors	Following FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices* (February 3, 2016), the human factors studies were conducted with the intended user population, use environment, and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
Biocompatibility	The biocompatibility test reports provided were conducted per ISO10993 series standard following Good Laboratory Practices and the representative product tested passed all acceptance criteria.
Battery Testing	The battery pack has been tested in accordance with IEC 62133.

<u>Clinical Testing</u>
Not Applicable

CONCLUSION

The subject device, Luminoah FLOW™ Enteral Nutrition System, FLOW™ Durable Pump, FLOW™ Administration Sets and FLOW™ Accessories, is substantially equivalent to the legally marketed predicate device, Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal (K153074) with respect to the intended use/indications for use, target populations, treatment method, and technological characteristics.