December 20, 2022

Cardinal Health LLC
Varela Fredy
Manager, Regulatory Affairs
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K221603

Trade/Device Name: Kangaroo OMNI™ Enteral Feeding Pump (385400);Kangaroo OMNI™ Feeding Set 500ml (B5FD);Kangaroo OMNI™ ENtelliSet 500ml (E5FD);Kangaroo OMNI™ Feeding Set 1000ml (B10FD);Kangaroo OMNI™ ENtelliSet 1000ml (E10FD);Kangaroo OMNI™ ENPlus Spike Set (BSPFD);Kangaroo OMNI™ ENtelliSet ENPlus Spike (ESPFD);Kangaroo OMNI™ Feeding Set 500ml with Flush Bag (B5FF);Kangaroo OMNI™ ENtelliSet 500ml with Flush Bag (E5FF);Kangaroo OMNI™ Feeding Set 1000ml with Flush Bag (E10FF);Kangaroo OMNI™ ENPlus Spike Set with Flush Bag (BSPFF);Kangaroo OMNI™ ENtelliSet ENPlus Spike with Flush Bag (ESPFF);Kangaroo OMNI™ Thick Formula ENtelliSet 500ml (E5FDR);Kangaroo OMNI™ Thick Formula ENtelliSet 500ml with Flush Bag (E5FFR);Kangaroo OMNI™ Thick Formula ENtelliSet 1000ml (E10FDR);Kangaroo OMNI™ Thick Formula ENtelliSet 1000ml with Flush Bag (E10FFR);Kangaroo OMNI™ Burette ENtelliSet (ER100);Kangaroo™ Power Cord with Adapter (384491);Kangaroo™ Adjustable Pole Clamp (384492);

Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZH
Dated: December 1, 2022
Received: December 2, 2022

Dear Varela Fredy:

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
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)*
K221603

Device Name
Kangaroo™ Omni Enteral Feeding Pump, Kangaroo™ Omni Feeding Sets, and Kangaroo™ Accessories

Indications for Use *(Describe)*

Intended for delivery of enteral fluids, including nutritional fluids and/or water to the gastrointestinal system via nasogastric, orogastric, nasojejunal, gastrostomy, and jejunostomy tubes. Not for use with neonates. Intended for any patients ages infant, child/adolescent and adult who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing. Intended to be used in hospital and acute care settings, as well as long term and home care settings by users ranging from clinicians to laypersons and patients. Some patients may need a caregiver to support using the device. It is intended to be used in both stationary and ambulatory conditions including ground and air transport while using backpack accessory.

The Kangaroo OMNI™ Enteral Feeding Pump and Feeding Set are intended to be used together as a system. Kangaroo OMNI™ Enteral Feeding Sets for administration of standard formula are able to be connected to access devices of all sizes that are ENFit™ compatible. The Kangaroo OMNI™ Thick Formula Feeding Sets for administration of thick formula can be used with access devices 8 Fr size or greater that are ENFit™ compatible.

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.

K221603 510(K) SUMMARY

Manufacturer's Name:	Cardinal Health LLC 3651 Birchwood Drive Waukegan, IL 60085
Corresponding Official:	Fredy Varela Manager, Regulatory Affairs
Telephone Number:	847.887.5781
E-mail:	fred.varela@cardinalhealth.com
Preparation Date:	December 19, 2022
Trade Name:	Kangaroo OMNI™ Enteral Feeding Pump, Kangaroo OMNI™ Feeding Sets and Kangaroo™ Accessories
Common or Usual Name:	Enteral Feeding pump, Infusion pump
Classification Name and Number:	Infusion Pump 21 CFR 880.5725 Class II Product Code: LZH
Primary Predicate Device:	Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal
Reference Device:	Kendall ePump Enteral Feeding Pump and Enteral Feeding Sets

Device Description

The Kangaroo OMNI™ Enteral Feeding Pump, Kangaroo OMNI™ Feeding Sets and Kangaroo™ Accessories consist of an enteral feeding pump and disposable enteral feeding sets along with accessories that deliver fluids via rotary peristaltic tension loop pumping to provide hydration and nutrition for those who do not have the ability to orally ingest food or drinks.

Intended Use/Indications for Use

Intended for delivery of enteral fluids, including nutritional fluids and/or water to the gastrointestinal system via nasogastric, orogastric, nasojejunal, gastrostomy, and jejunostomy tubes. Not for use with neonates. Intended for any patients ages infant, child/adolescent and adult who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing. Intended to be used in hospital and acute care settings, as well as long term and home care settings by users ranging from clinicians to laypersons and patients. Some patients may need a caregiver to support using the device. It is intended to be used in both stationary and ambulatory conditions including ground and air transport while using backpack accessory.

The Kangaroo OMNI™ Enteral Feeding Pump and Feeding Set are intended to be used together as a system. Kangaroo OMNI™ Enteral Feeding Sets for administration of standard formula are able to be connected to access devices of all sizes that are ENFit™ compatible. The Kangaroo OMNI™ Thick Formula Feeding Sets for administration of thick formula can be used with access devices 8 Fr size or greater that are ENFit™ compatible.

Substantial Equivalence Discussion

Feature	Predicate Device Kangaroo™ Connect K153074	Subject Device Kangaroo™ OMNI K221603 (current submission)	Subject vs. Predicate Device Differences Substantial Equivalence
Intended Use/Indications for Use	Intended to deliver nutritional formula at a controlled rate to the gastrointestinal system of a patient 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.	Intended for delivery of enteral fluids, including nutritional fluids and/or water to the gastrointestinal system via nasogastric, orogastric, nasojejunal, gastrostomy, and jejunostomy tubes. Not for use with neonates. Intended for any patients ages infant, child/adolescent and adult who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing. Intended to be used in hospital and acute care settings, as well as long term and home care settings by users ranging from clinicians to laypersons and patients. Some patients may need a caregiver to support using the device. It is intended to be used in both stationary and ambulatory conditions including ground and air transport while using backpack accessory. The Kangaroo OMNI™ Enteral Feeding Pump and Feeding Set are intended to be used together as a system. Kangaroo OMNI™ Enteral Feeding Sets for administration of standard formula are able to be connected to access devices of all sizes that are ENFit™ compatible. The Kangaroo OMNI™ Thick Formula Feeding Sets for administration of thick formula can be used with access devices 8 Fr size or greater that are ENFit™ compatible.	General purpose of the subject device or its function, condition and patient population are the same as predicate device. Subject device feature is substantially equivalent to that of the predicate device
Technological Characteristics	Peristaltic pumping action	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Design (Pump)	The pump incorporates a menu-controlled, operating system which contains on board custom software designed to allow the user	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device

Feature	Predicate Device Kangaroo™ Connect K153074	Subject Device Kangaroo™ OMNI K221603 (current submission)	Subject vs. Predicate Device Differences Substantial Equivalence
	to set feed rates and volumes as well as other feeding options		
Free Flow Mechanism	Anti-Free Flow Valve	Stopcock Valve	Difference does not introduce or raise concerns regarding the safe and effective use of the subject device.
Feed Capability	Yes	Same	Subject device feature is substantially equivalent to that of the predicate device
Feed and Flush Capability	No	Yes	Difference is considered an added benefit/option for the user, and does not introduce or raise concern regarding the safe and effective use of the subject device
Thick Formula Capability	No	Yes	Difference is considered a added benefit/option for the user, and a design improvement that does not introduce or raise concern regarding the safe and effective use of the subject device. Clinical benefits offered by thick formula feeding option outweigh the risks associated with it.
Flow Monitoring	Yes, 2 Ultrasonic sensors	Same 2 ultrasonic sensors and 1 new force sensor	Difference is considered a design improvement that does not introduce or raise concerns regarding the safe and effective use of the subject device.
Occlusion Detection	Yes, Upstream and Downstream	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Accuracy (Standard Formula Feeding Sets)	±5%	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Accuracy (Thick Formula Feeding Sets)	N/A	±10%	Difference is considered a design improvement that does not introduce or raise concern regarding the safe and effective use of the subject device
Delivery Rate Range	1-600ml in 1ml increments	1 to 400mL per hour in 1mL increments (Standard Formula Feeding Sets) 1 to 200mL per hour in 1mL increments (Thick Formula Feeding Sets)	Difference is considered a design improvement that does not introduce or raise concern regarding the safe and effective use of the subject device
Dose Range	1-3000ml in 1ml increments	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Power requirements	120V, 60Hz, 1Amp	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Autoprime	Yes	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Display	Color TFT (320x240 pixels)	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Maximum Occlusion Pressure	20 psi	16 psi	Difference is considered a design improvement that does not introduce or raise concerns regarding the safe and effective use of the subject device.

Feature	Predicate Device Kangaroo™ Connect K153074	Subject Device Kangaroo™ OMNI K221603 (current submission)	Subject vs. Predicate Device Differences Substantial Equivalence
Size	3.9" x 6.1" x 1.6"	5.5" x 6.8" x 2.6"	Differences do not introduce or raise concern regarding the safe and effective use of the subject device. Subject device feature is substantially equivalent to that of the predicate device
Weight	0.73 lbs (0.33 kg)	1.7 lbs (770 grams)	Differences do not introduce or raise concern regarding the safe and effective use of the subject device. Subject device feature is substantially equivalent to that of the predicate device
Pole Clamp Mountable	Yes	same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Battery Life	24 hours	20 hours	Difference is considered a design improvement that does not introduce or raise concern regarding the safe and effective use of the subject device
Battery Recharge Time	7 hours	12 hours	Difference is considered a design improvement that does not introduce or raise concern regarding the safe and effective use of the subject device
Battery Operation Indicator	Yes	same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Operating Temperature Range	5°-40°C (41°-104°F) at 93% R.H. (non-condensing)	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Storage Temperature Range	0°-50°C (32°-122°F) at 93% R.H. (non-condensing)	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Medical and Electrical Safety Standards	IEC 60601-1 ANSI/AAMI ES 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	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Degree of Protection Against Electrical Shock	Class 2 Type BH per IEC Standards Pass	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Degree of Protection for liquid ingress	IP26 = Water Jet proof per IEC 60529 Pass	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
EMC/ EMI and ESD standards	IEC 60601-1-2 Parts 1 and 2	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Power Adapter	Yes	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the predicate device
Rechargeable Battery	Lithium Ion	Same	Subject device feature is the same as the predicate device. Subject device feature is substantially equivalent to that of the

Feature	Predicate Device Kangaroo™ Connect K153074	Subject Device Kangaroo™ OMNI K221603 (current submission)	Subject vs. Predicate Device Differences Substantial Equivalence
			predicate device
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: System Error Dead Battery Valve Error Rotor Stuck Cassette Dislodged Cassette Error Sensor Error (1 - 3) Patient Tube Blocked Feed Error Flush Error Low Battery Caution Low Battery Notice Pump Inactive Notifications: Feeding Complete Feeding Incomplete Settings Locked	Differences are considered design improvements that do 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	Displayed as Timed Pause Vol delivered at maximum time interval	Difference does not introduce or raise concern regarding the safe and effective use of the subject device. Subject device feature is substantially equivalent to that of the predicate device

Performance Testing

A safety assurance case, as recommended by the FDA guidance document, Infusion Pumps Total Product Life Cycl*e*, was provided for the Kangaroo™ Omni Enteral Feeding Pump, Kangaroo™ Omni Feeding Sets, and Kangaroo™ Accessories. The stated top-level claim of the assurance case is:

The Kangaroo OMNI™ System is 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 assurance case 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 software contained in medical devices" for a Major Level of Concern and FDA guidance document "Infusion pump total product life cycle"
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 Kangaroo OMNI™ Enteral Feeding Pump 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.

Device Performance	The essential 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 of essential performance attributes • Reliability testing • Flow rate accuracy testing across all operating conditions • Alarm detection
Human Factors	Follow 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.

Clinical Testing

Not Applicable

Conclusions

The differences between the predicate and the subject device do not introduce or raise concerns regarding the safe and effective use of the subject device.

The subject device, Kangaroo OMNI™ Enteral Feeding Pump, Kangaroo OMNI™ Feeding Sets and Kangaroo™ 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.