DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 6, 2016

Covidien
Ms. Karin Desjardins
Regulatory Affairs Manager
15 Hampshire Street
Mansfiled, Massachusetts 02048

Re: K153074
Trade/Device Name: Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZH
Dated: May 16, 2016
Received: May 17, 2016

Dear Ms. Desjardins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153074

Device Name
Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal

Indications for Use *(Describe)*
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.

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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K153074 510(K) SUMMARY

Manufacturer's Name:	Covidien 15 Hampshire Street Mansfield, MA 02048
Corresponding Official:	Karin Desjardins Manager, Regulatory Affairs Patient Monitoring & Recovery Medtronic
Telephone Number:	(508) 452-1856
E-mail:	karin.d.desjardins@medtronic.com
Preparation Date:	June 28, 2016
Trade Name:	Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal
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:	K143263 - Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets
Secondary Predicate Device:	K141789 - Plum 360™ Infusion system with Hospira MedNet™ / Smart Card Plug 'n' Play CE 3.0 Module

Device Description

The Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets and Kangaroo™ Connect Portal consists of a wireless enabled enteral feeding pump and disposable enteral feeding sets that deliver formula via rotary peristaltic tension loop pumping to provide nutrition for those who do not have the ability to orally ingest food. The new Kangaroo™ Connect Enteral Feeding Pump wireless accessories include a communication hub and the Kangaroo™ Connect Portal. The communication hub collects short-range data from the pump through a Zigbee signal and sends the data through either WiFi or a cellular signal to the device cloud where the Kangaroo™ Connect Portal can access the data for monitoring. The wireless enabled pump, when used in conjunction with the wireless accessories, will provide a platform for remote data collection allowing clinicians to more efficiently monitor feeding rates and review actual history of nutritional delivery.

Intended 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.

Substantial Equivalence Discussion

	Primary Predicate Device	Secondary Predicate Device	Subject Device
510(k) Number	K143263	K141789	K153074
Device Name	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets	Plum 360™ Infusion system with Hospira MedNet™ / Smart Card Plug 'n' Play CE 3.0 Module	Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets, and Kangaroo™ Connect Portal
Device Description	Enteral feeding pump and disposable enteral feeding sets	Infusion Pumps, Infusion safety management software & Intravascular Administration Sets	Enteral feeding pump and disposable enteral feeding sets
Intended 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 clinicians	Indicated for use in parenteral, enteral and epidural therapies and the administration of whole blood and blood products.	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
Intent of Wireless Connectivity	Not applicable – no wireless features	Allows communication between the Infusion Pump, Hospira MedNet™ server and the facility's communication systems.	Provide a platform for remote data collection.
Sterility	Non Sterile feeding sets	Not known	Non Sterile feeding sets

	Primary Predicate Device	Secondary Predicate Device	Subject Device
Technological 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.	Not known	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.
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.	Not known	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.
Rechargeable Battery	lithium ion	Not known	lithium ion
Graphic Display	multi-color	Not known	multi-color
Water Ingress Rating	IP26	Not known	IP26
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)	Not known	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)

	Primary Predicate Device	Secondary Predicate Device	Subject Device
Includes Anti-Free Flow Valve	Yes	Not known	Yes
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	Not known	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

Discussion of Differences

There are no differences between the indications for use of the predicate, K143263 and the subject device. The primary difference between the predicate Kangaroo™ Connect Enteral Feeding Pump cleared under K143263 and the proposed Kangaroo™ Connect Pump is an enabled wireless processor. To facilitate wireless capability, Covidien intends to introduce new accessories to be used in conjunction with the wireless-enabled Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets. the new accessories include a communication hub and Connect Portal. The wireless enabled pump, in conjunction with new wireless accessories, will provide a platform for remote data collection allowing clinicians to more efficiently monitor feeding rates and review actual history to help improve patient outcomes.

Discussion of Performance Testing

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

The Kangaroo™ Connect 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 assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments.

The following assurance claims were used to support the design safety goals:

- System design is acceptably safe
    - All relevant hazards have been identified and controlled
        - System wise hazard analyses are adequate
        - All identified hazards have at least one corresponding control
        - All requirements have been implemented and verified
    - Device design ensures safe behavior
        - Reliability requirements are met
- System in use is acceptably safe
- Development and supporting processes are adequate
    - Quality assurance is adequate
    - Software development is adequate
    - Risk Management process is adequate
        - Hazard identification and mitigation are complete
        - All controls have been correctly implemented in the final device design

The assurance case also included additional goals, which were not relied on to support the design safety review, but were included to support the top level structure.

- Manufactured System is acceptably safe
- System disposal is acceptably safe

The following Performance Testing evidence was included in the assurance case:

- System Verification and Validation activities
- Wireless enabled-disabled performance testing of essential performance attributes
    - Flow Rate Accuracy
    - Downstream Occlusion Detection
    - Pump Alarms (Feed Bag Empty, Supply Tube Blocked, Cassette Dislodged, Rotor Stuck, Cassette Error)
- Cleaning and disinfection validation and instructions
- Human factors testing to evaluate the usability of the device
- Electrical Safety testing in accordance with applicable IEC standards (IEC 60601-1:2005 AAMI ES 60601-1:2005, Medical electrical equipment-Part1: General requirements for basic safety and essential performance)
- Electromagnetic compatibility evaluation in accordance with applicable standards (IEC 60601-1-2:2014, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.)
- Software verification and validation testing, as recommended by the FDA guidance document Infusion Pump Total Product Life Cycle

Clinical Testing

Clinical evaluations were not submitted and not needed.

Conclusions

This information provided within this pre-market notification demonstrates that the Kangaroo™ Connect Enteral Feeding Pump, Kangaroo™ Connect Enteral Feeding Sets, and Kangaroo™ Connect Portal are substantially equivalent to the legally marketed predicate device.