DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 16, 2017

Covidien (dba Medtronic)
Alexis Erazo
Sr. Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K163002
Trade/Device Name: Kangaroo™ Feeding Tube with IRIS Technology
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, PIF
Dated: April 12, 2017
Received: April 13, 2017

Dear Alexis Erazo:

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,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163002

Device Name
Kangaroo™ Feeding Tube with IRIS Technology

Indications for Use *(Describe)*
The Kangaroo™ Feeding Tube with IRIS Technology utilizes a video stream to aid a trained user during placement into the stomach or small bowels for the administration of nutrition, fluids, and medications by the naso-enteric route for patients aged 18 years and older who have an intact gastrointestinal tract, but are physically unable to manage nutritional intake through normal mastication and deglutition. Prior to commencing administration, confirm correct tube placement per institutional protocol. Placement of the tip of the device into the small bowel should only be attempted by clinicians with expertise in small bowel placement.

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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510(k) Summary
Kangaroo™ Feeding Tube with IRIS Technology

Preparation date:

May 9, 2017

Manufacturer's Name:

Covidien
15 Hampshire Street
Mansfield, MA 02048

Corresponding Official:

Alexis Erazo
Sr. Regulatory Affairs Specialist
Phone: 508-452-4673
Alexis.erazo@medtronic.com

Name of Medical Device:

Trade Name:	Kangaroo™ Feeding Tube with IRIS Technology
Common Name:	Tubes, gastrointestinal
Classification Name:	Gastrointestinal tube and accessories
Regulation Number:	21 CFR 876.5980
Product Code:	KNT
	PIF (Secondary)
Class:	II

Identification of Predicate Device:

510(k) Number	K123555
Device Description	Kangaroo™ Feeding Tube with IRIS Technology
Submitter	Covidien

Device Description:

The Kangaroo™ Feeding Tube with IRIS Technology is a small-bore nasogastric enteral access catheter. The gastrointestinal tube includes an external proximal access port for connection to enteral feeding sets and to syringes with ENFit connector. The tubing is constructed with a radiopaque material and with a hydrophilic coating to assist with insertion of the tube. The stylet is made of

specially designed metal wire, which may be utilized to assist with tube placement. The tube is equipped with external markings in units of centimeters to assist in estimating the length of tube inserted into the alimentary tract. The device may be connected to a console, which allows for viewing a video stream and capture of camera images an interface cable connects the feeding tube to the console. LED light is incorporated into the distal tip of the tube and the light will power on only when properly connected to the console with the interface cable.

The Kangaroo Feeding Tube with IRIS Technology will continue to be available in three (3) sizes and three (3) lengths: 8 Fr, 10 Fr, 12 Fr and 36", 43" and 55". The Kangaroo Feeding Tube with IRIS Technology is not made with DEHP and are non-sterile. The product and packaging is not made with natural rubber latex.

Intended Use/Indications for Use:

The Kangaroo™ Feeding Tube with IRIS Technology utilizes a video stream to aid a trained user during placement into the stomach or small bowels for the administration of nutrition, fluids, and medications by the naso-enteric route for patients aged 18 years and older who have an intact gastrointestinal tract, but are physically unable to manage nutritional intake through normal mastication and deglutition. Prior to commencing administration, confirm correct tube placement per institutional protocol. Placement of the tip of the device into the small bowel should only be attempted by clinicians with expertise in small bowel placement.

Product Comparison Summary:

The modified Kangaroo™ Feeding Tube with IRIS Technology has the same intended use and improved visual optics as compared to the predicate device (K123555). Verification testing completed on the modified Kangaroo™ Feeding Tube with IRIS Technology demonstrates that the modifications do not raise new questions of safety and efficacy and that the proposed device is as safe and effective as the legally marketed K123555 Kangaroo™ Feeding Tube with IRIS Technology.

	Predicate Kangaroo Feeding Tube with IRIS Technology (K123555)	**Proposed Kangaroo Feeding Tube with IRIS Technology**
Intended Use/ Indications for Use	The Kangaroo™ Feeding Tube with IRIS Technology utilizes a video stream to aid a trained user during placement into the stomach or small bowels for the administration of nutrition, fluids, and medications by	The Kangaroo™ Feeding Tube with IRIS Technology utilizes a video stream to aid a trained user during placement into the stomach or small bowels for the administration of nutrition, fluids, and medications by

	Predicate Kangaroo Feeding Tube with IRIS Technology (K123555)	Proposed Kangaroo Feeding Tube with IRIS Technology
	the naso-enteric route for patients aged 18 years and older who have an intact gastrointestinal tract, but are physically unable to manage nutritional intake through normal mastication and deglutition. Prior to commencing administration, confirm correct tube placement per institutional protocol. Placement of the tip of the device into the small bowel should only be attempted by clinicians with expertise in small bowel placement.	the naso-enteric route for patients aged 18 years and older who have an intact gastrointestinal tract, but are physically unable to manage nutritional intake through normal mastication and deglutition. Prior to commencing administration, confirm correct tube placement per institutional protocol. Placement of the tip of the device into the small bowel should only be attempted by clinicians with expertise in small bowel placement.
Classification Name	Tubes, Gastrointestinal (and Accessories)	Tubes, Gastrointestinal (and Accessories)
Regulation Reference	21 CFR 876.5980	21 CFR 876.5980
Product Code	KNT	KNT, PIF
Classification	II	II
Prescription Use	Rx	Rx
Sterilization	Non-Sterile	Non-Sterile
Labeled Single Use	Single Use	Single Use
Shelf Life	2 Years	2 Years
French Sizes	8Fr 10Fr 12Fr	8Fr 10Fr 12Fr
Available Tube Lengths	36” 43” 55”	36” 43” 55”
Proximal End Connections	ENFit Connection System	ENFit Connection System
Proximal Access Port (ENFit)	Yes, allows for irrigation (flushing), manual fluid/ medication access, and aspirate collection	Yes, allows for irrigation (flushing), manual fluid/ medication access, and aspirate collection
ISO 80369-3 Compliance (ENFit Connection)	Yes	Yes
Placement Stylet Included	Yes	Yes
Shaft Design	Single lumen	Single lumen
Shaft Flow Outlet	2 eyes at distal end	2 eyes at distal end
Measurement Markings	Yes, cm units	Yes, cm units

	Predicate Kangaroo Feeding Tube with IRIS Technology (K123555)	Proposed Kangaroo Feeding Tube with IRIS Technology
Camera and Electronics	Yes	Yes
Coating (tip)	Water-activated Hydromer lubricant	Water-activated Hydromer lubricant

Non-Clinical Performance Data:

Laboratory testing was completed to support substantial equivalence between the modified device and the predicate device. The modified device was evaluated to demonstrate compliance to the below standards.

- IEC 60601-1:2005 with corrigenda and U.S. national deviations were considered against standard AAMI ES60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- FDA's Guidance for Industry, Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, issued on August 21, 2008
- EN 1615:2000, Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing
- BS EN 1618:1997 Catheters Other than Intravascular Catheters - Test Methods for Common Properties
- AAMI/CN3 (PS):2014 Part 3 Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications

The following testing was conducted to demonstrate that the modified device continues to meet product specifications and support the determination of substantial equivalence.

Electrical Safety

- ISO 60601-1 3rd Ed.:2005 and ISO 60601-1-2 Ed. 3.0:2007 Medical Electrical Equipment Safety and Essential Performance
- Leakage Current Testing
- Dielectric Voltage Withstand
- Evaluation of Magnetic Field Interactions, Heating, and Artifacts

Storage and Stability

- Storage Stability
- ISTA 2A Functional Evaluation

Feeding Tube Bench Testing

- Feeding Tube Fluid Isolation Test Report
- Feeding Tube Wire Slip in Co-extrusion
- Feeding Tube Stylet Penetration Force
- Feeding Tube Conductors Break Strength
- Feeding Tube Anatomical Insertion Force Test
- Feeding Tube Placement and Useful Life
- Feeding Tube Water Leak Test (30 Day Gastric)
- Feeding Tube Distal Subassembly Tensile Test
- Stylet Introduction Force
- Stylet Removal Force
- Flow and Functionality Analysis
- Image Head Length Test Report
- Image Head Illumination Output
- Image Head External Temperature
- Electrical Continuity Analysis

Optical Bench Testing

- Image Head Capture
- Image Head Depth of Field Test Report
- Image Head Field of View Test Report
- MRI Image Testing

Animal Testing

- Temperature Testing of IRIS Technology Feed Tube in Porcine Tissue

Clinical Data:

Clinical evaluations were not relied upon for evidence of safety of effectiveness, or for a determination of substantial equivalence.

Conclusion:

Based on the nonclinical tests performed on the proposed device, the modified Kangaroo Feeding Tube with IRIS Technology is as safe and effective as the legally marketed Kangaroo Feeding Tube with IRIS Technology (K123555). The information provided within this 510(k) demonstrates that the modified Kangaroo Feeding Tube with IRIS Technology is equivalent to the predicate device.