2.0 510(k) Summary

Kangaroo™ Feeding Tube with IRIS Technology

In accordance with section 513(i) of the SMDA and as defined in 21 CFR Part 807.92 this summary is submitted by:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: March 4, 2014

a. Contact Person

James Welsh
VP, Regulatory Affairs
Medical Supplies
Covidien
Telephone: (508) 261-8532
Fax: (508) 261-8461

b. Name of Medical Device

Common Name: Tubes, gastrointestinal

U.S. FDA Classification Product Code: KNT

U.S. Regulation Description: Gastrointestinal tube and accessories, 21 CFR 876.5980

Proprietary / Trade Name: Kangaroo™ Feeding Tubes with IRIS Technology

c. Identification of Legally Marketed Device(s)

- Covidien DOBBHOFF™ Dual Port Feeding Tubes, with and without Flow-Through Stylet, K112511
- Corpak CORTRAK™ System, reference predicate for the replacement stylet, K080679

d. Device Brief Description

The Kangaroo™ Feeding Tubes with IRIS Technology are small bore nasogastric enteral access catheters. These gastrointestinal tubes include an external proximal access port for connection to enteral feeding sets and to syringes with either oral tip or catheter tip designs. 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 tubes are each equipped with external markings in units of centimeters to assist in measuring the length of tube inserted into the alimentary tract. These devices may connect to a console which allows for viewing a video stream and capture of camera images from the distal end of the feeding tube during placement. In order to transmit the images, an interface cable connects the feeding tube to the console. LED light is incorporated into the distal tip of the tubes and the light will power on only when properly connected to the console with the interface cable.

e. Device Intended Use

Enteral feeding tubes provide nutritional support for patients who require feedings of liquids as a substitute for solid food. These enteral access gastrointestinal devices are catheters for insertion via natural naso/oro-enteric passages and intended for the transfer of nutritional and hydrating fluids, as well as medications, into the alimentary tract. The video stream feature is intended as an adjunct to current placement practices for assisting clinical practitioners who place feeding tubes. This describes the device intended use.

The indications for use are as follows: 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.

f. Product Comparison Summary

The proposed and predicate catheters are all intended for patients who require fluid feedings as a substitute for solid food. These products are catheters that have the same intended use, the same function, the same general technological characteristics, and are for connection to the same types of devices.

g. Nonclinical Testing

The enteral feeding catheters have been evaluated against the design and standard performance specifications of *EN1615:2000, Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing.* Biocompatibility testing has demonstrated that the proposed device meets guidelines presented by the FDA Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.
The device was evaluated to the requirements of AAMI ES60601-1:2005 and of IEC 60601-1-2:2007 for the safety of medical electrical equipment. The proposed device and accessories do not incorporate electronic programmable systems which may control device parameters or monitor clinical parameters. However, the imaging system software was developed under the framework for lifecycle processes provided in standard IEC 62304:2006.

h. Clinical Testing

Clinical evaluations were not relied upon for evidence of safety or effectiveness, nor for a determination of substantial equivalence.

i. Conclusions

The information provided within this pre-market notification demonstrates that the Kangaroo™ Feeding Tubes with IRIS Technology have no difference that would affect the safety or effectiveness of the devices as compared to the predicate devices.

End of Summary

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

April 9, 2014

Covidien
Jim Welsh
VP, Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048

Re: K123555
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
Dated: April 2, 2014
Received: April 3, 2014

Dear Jim Welsh,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

1.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K123555

Device Name: Kangaroo™ Feeding Tube with IRIS Technology

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.

Prescription Use ___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2014.04.08 12:06:55 -04'00'