DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 2, 2015

Covidien
Wei Zhao, M.D.
Senior Director, Regulatory Affairs
15 Hampshire Street
Mansfeild, MA 02048

Re: K143018
Trade/Device Name: Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: March 3, 2015
Received: March 6, 2015

Dear Wei Zhao,

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,

Herbert P. Lerner -S

for 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)*
K143018

Device Name
Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors.

Indications for Use *(Describe)*

The Kangaroo™ Feeding Tube Extension Sets with ENFit small bore connectors are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition or medication from an enteral feeding syringe through to any feeding tube which will accept a connector for enteral applications.

The device is intended for neonates and infants who require enteral feeding.

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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2.0 510(k) Summary

Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors

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

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: October 17, 2014

a. Contact Person

Wei Zhao, M.D.
Senior Director, Regulatory Affairs
Covidien
Telephone: (508) 261-8404
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b. Name of Medical Device

Common Name: tube, feeding

U.S. FDA Classification Product Code: PIF

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

Proprietary / Trade Name: Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors

c. Identification of Legally Marketed Device(s)

Covidien Kangaroo™ Enteral Feeding Extension Sets, K973409

d. Device Brief Description

The Kangaroo™ Feeding Tube Extension Sets with ENFit small bore connectors are sterile, disposable medical devices designed to deliver nutrition to patients who cannot obtain nutrition or liquid by mouth, are unable to swallow safely, or need nutritional supplementation. The proposed set is intended as a conduit between the enteral feeding formula container (mostly enteral feeding syringe) and feeding tube. The device is designed with a single lumen microbore PVC tube with ENFit small bore connectors at both ends. During enteral feeding therapy, mainly for neonates and infants, there are situations when the feeding tube extension set is required to connect the syringe to patient feeding tube when the

distance between the patient and the source of enteral feeding demands additional length of tube.

Device Intended Use

The Kangaroo™ Feeding Tube Extension Sets with ENFit small bore connectors are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition or medication from an enteral feeding syringe through to any feeding tube which will accept an ENFit small bore connector for enteral applications.

The device is intended for neonates and infants who require enteral feeding.

e. Product Comparison Summary

The proposed and predicate enteral feeding devices are all intended for patients who cannot obtain nutrition by mouth, are unable to swallow safely, or need nutritional supplementation. These products have the same intended use, the same function, and the same general technological characteristics. Both the predicate and proposed products are designed with the single lumen microbore PVA tubing. They both are intended for connection with a syringe operated with syringe pump at proximal end and an enteral feeding tube at the distal end. The majority of the parts for both the proposed and predicate sets are made with the same material. The variation of the materials for certain components has been proven biocompatible and effective. The major technological enhancement is the incorporation of new ENFit connectors which are compliant to ISO 80369-3, into the proposed Kangaroo™ Feeding Tube Extension Sets. The ENFit connectors are part of an industry wide effort to address misconnections by adopting a uniform connector that has been engineered to meet the objective of IS0 80369-1, small-bore connectors for liquids and gases in healthcare applications - part 1: general requirements. At the proximal end of the device, a female syringe luer lock connector is designed for the predicate extension set. A male ENFit connector is offered for the proposed extension set. At the distal end of the product, the connection design for the predicate extension set is a non-IV compatible stepped connector. For the proposed extension set, the connection design is a female ENFit connector. Other additions to the proposed products include two lengths, option of a medication port with male ENFit connector, and slide clamps to the tubing. These variations do not alter the intended use of the device, nor impact the safety and effectiveness of the product.

f. Nonclinical testing

- Biocompatibility testing has demonstrated the biological safety of parts of the proposed extension sets which may indirectly contact the patient.

- Stability testing evaluated the properties of the Kangaroo™ Feeding Tube Extension Sets after accelerated aging in support of the product expiration date.

- Dimensional analysis was conducted for critical dimensions of the Kangaroo™ Feeding Tube Extension Sets, in accordance with ISO 80369-3, Small-bore

connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. The testing demonstrates the proposed devices conform to the criteria in Table B.2 of ISO 80963-3.

- Study performed on the Kangaroo™ Feeding Tube Extension Sets with ENFit Connectors included the tests listed below, in accordance with ISO 80369-3, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods. The testing demonstrates the proposed devices conform to the requirements of ISO 80963-3.

Individual Test Defined in ISO 80369-3	**Requirement Defined in ISO80369-3**	**Test Method Defined in ISO 80369-20**
Fluid Leakage	Clause 6.2	Annex C
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H
Disconnection by unscrewing	Clause 6.7	Annex I

- Flow testing was conducted and has demonstrated that the proposed extension sets are substantially equivalent to the performance of the predicate device.

- The risk associated the misconnection of the ENFit connector has been assessed at length and captured in the following documents, which are located in Master File 2258.
    - PG Lock Misconnection Data with Failure Modes and Effects Analysis (FMEA) 2014-01-9
    - 3595-0501-04 Enteral Connector Misconnection Assessment
    - Enteral Connection Risk Management Report Rev 2.0
    - PG Lock Misconnection Risk Assessment Report 041513

- Usability and human factors testing was conducted as part of the design of the ENFit connector, and is captured in the following document, which is located in the Master File 2258.
    - Human Factors Validation Study – Enteral Connectors Final Report

g. Clinical testing

Clinical evaluations were not relied upon for the determination of substantial equivalence to the predicate device based on the device classification, sufficient safety and functional performance information provided in the submission.

h. Conclusions

The information provided within this pre-market notification demonstrates that the Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors have no difference that would affect the safety or effectiveness of the devices as compared to the predicate devices and provides reasonable assurance of the safety and effectiveness of the device to demonstrate substantial equivalence.

End of Summary