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510(k) Summary

12-May-10

MAY 20 2010

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Official Contact: Alan Reid

Proprietary or Trade Name: Pediatric Enteral Feeding Tube and Accessories
Pediatric Enteral Feeding Tube Extension sets

Common/Usual Name: Feeding Tube or NG /OG Tube

Classification Name: Tubes, Gastrointestinal (and Accessories)

Predicate Devices: NeoDevices – K020005 - Infant Feeding Tubes
NeoChild – K082710 - Infant Feeding Tube
Argyle / Kendall – K820442 Feeding Tube

Device Description:
The proposed modification to the Pediatric Enteral Feeding Tubes and accessories is to add additional materials that the feeding tube may be made from, i.e., PVC, silicone, and polyurethane. In addition, we offer accessories: an enteral feeding extension set and syringe with non-IV connector. These may be sold with the Enteral Feeding tubes or separately. There is an option of the connectors to be provided as standard IV luer lock or a non-IV connector. In all cases the feeding tube and accessories are marked "For enteral feeding only".

The enteral feeding tubes are provided in various diameters (4, 5, 6.5, 8, 10 Fr) and various lengths. They have an integral female fitting. There are 2 eyelets near the tip of the tube. They have markings along the shaft of the tubing and an integral radiopaque line. They are provided sterile.

The Enteral extension sets are provided in various lengths and various configurations of components.

Indications for Use:
The Pediatric Enteral Feeding tubes are intended to be placed into the stomach to permit the introduction of fluids as directed by the physician. They are intended for nasogastric or orogastric placement, limited to < 30 day placement and not intended for transpyloric placement.

The Pediatric Enteral Feeding Tube Extension sets are used to provide a connection between feeding formula bag and the feeding tube. Extensions sets are offered in non-IV fittings and IV fittings (which have been marked "For enteral feeding only").

Environment of Use:
Hospital or environments where placement of a feeding tube is required.

Comparison to Predicate Devices:

Attribute	**Proposed device**	**Predicates**
Indications General	To be placed into the stomach to permit the introduction of fluids as directed by the physician.	To be placed into the stomach to permit the introduction of fluids as directed by the physician. K020005 – Infant Feeding Tube
Type of placement	Nasogastric or orogastric Not for transpyloric placement.	Nasogastric or orogastric. Not for transpyloric placement. K020005 – Infant Feeding Tube
Length of placement	< 30 days	< 30 days - K020005 – Infant Feeding Tube
Intended for single patient use	Yes	Yes - K020005 – Infant Feeding Tube
Prescription required	Yes	Yes - K020005 – Infant Feeding Tube
Intended population	Neonates, Infants, Pediatrics	Neonates / Infants / Pediatrics -K020005 – Infant Feeding Tube
Intended Environment of Use	Hospital or environments where placement of a Feeding tube is required.	Hospital or environments where placement of a Feeding tube is required. K020005 – Infant Feeding Tube
Design Features		
Provided in various diameters	4, 5, 6.5, 8, 10 Fr	Yes –K020005 – Infant Feeding Tube (4, 5, 6.5, 8 Fr) Yes – K820442 – Argyle / Kendall (10 Fr)
Extension sets for use with enteral feeding tubes to deliver fluids and connector between the feeding tube and the fluid source	Yes, made of PVC Available in various lengths Intended for use with enteral feeding tubes	Yes, made of PVC K890396 – Multi-Med enteral feeding set K082710 - NeoChild extension set
Connector options	Non-IV slip fit female connection Must be used with the specified syringe with integral mating non-IV connector Standard IV luer	IV and Non-IV K082710 – NeoChild with non-IV connector
Two (2) eyelet holes near tip	Yes	Yes - K020005 – Infant Feeding Tube
Radiopaque line	Yes	Yes - K020005 – Infant Feeding Tube
Markings along the length of the tubing	Yes	Yes - K020005 – Infant Feeding Tube
Materials		
Tubing	PVC Silicone Polyurethane	K020005 – Infant Feeding Tube - PVC K082710 – NeoChild – silicone, polyurethane

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Attribute	Proposed device	Predicates
Packaging		
Sterile	Feeding tubes Extension Sets Syringe – non-sterile	K020005 – Infant Feeding Tube K890396 – Multi-Med K082710 - NeoChild – Infant Feeding Tube and accessories with non-IV connector
Offered with and without extension sets of various lengths and connectors	Yes	K082710 - NeoChild – Infant Feeding Tube and accessories with non-IV connector
Performance Testing		
None under Section 514	Yes	Yes
Performance testing was performed in accordance to ISO 594/1 BS EN 1615:2000 BS EN 1618:1997	Gauging of 6% luer conical fittings Gauging of non-luer conical fittings Tensile strength and properties of tubing and connectors Air leakage test of tubing and connectors Liquid leakage test of tubing and connectors Separation force Stress cracking Unscrewing torque of fitting assembly Ease of assembly Resistance to overriding the threads of lugs of the fitting The above listed performance / bench tests were performed and shown to demonstrate that the Enteral Feeding tube, accessories and Enteral extensions sets either met the requirements of the industry standards or were substantially equivalent to the predicate devices.	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

Mr. Alan Reid
c/o Mr. Paul E. Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134-2958

MAY 20 2010

Re: K092628
Trade/Device Name: Pediatric Enteral Feeding Tube and Accessories
Pediatric Enteral Feeding Tube and Extension sets
Regulation Number: 21 CFR §876. 5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 12, 2010
Received: May 14, 2010

Dear Mr. Dryden:

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.

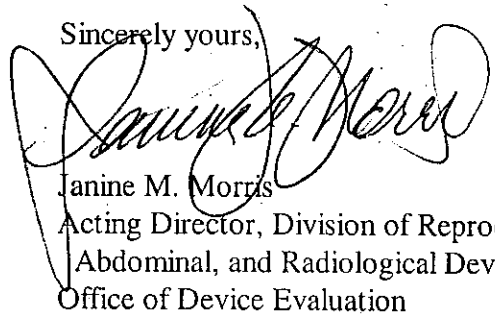
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K092628

Device Name: Pediatric Enteral Feeding Tube and Accessories
Pediatric Enteral Feeding Tube Extension sets

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092628