NOV - 9 2005

Non-Confidential Summary of Safety and Effectiveness

13-Oct-05

ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055

Tel (317) 335-3780
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Official Contact: Paul Dryden - President

Proprietary or Trade Name: Infant Feeding Tube

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

Classification Name: Tubes, Gastrointestinal (and Accessories)

Predicate Devices: ProMedic - Infant Feeding Tubes – K020005

Device Description:

The Infant Feeding Tube is a small diameter tube of various diameters, 5, 6, and 8 French, and lengths, 14.5", 35" and 41". It has an integral female luer fitting. There are 2 eyelets near the tip of the tube. It has marking along the shaft of the tubing and an integral radiopaque line. It is provided sterile.

Indications for Use:

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The Infant Feeding tube is intended to be placed into the stomach to permit the introduction of fluids as directed by the physician.

Intended for nasogastric or orogastric placement. Limited to less than 30 day placement.

Not intended for transpyloric placement.

Environment of Use --

Hospital or environment where placement of a feeding tube is required.

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Comparison to Predicate Devices:

Attribute	Proposed device	Predicate ProMedic Infant Feeding Tube – K020005
Indications for Use		
To be placed into the stomach to permit the introduction of fluids as directed by the physician. Nasogastric or orogastric placement.	Yes	Yes
Intended for single patient use for a duration of < 30 days	Yes	Yes
Prescription	Yes	Yes
Intended population infants	Yes	Yes
Intended Environment of Use - Hospital or environments where placement of a Feeding tube is required.	Yes	Yes
Design Features		
Provided in various diameters	5,6,8 Fr	5,6,8 Fr
Standard slip fit female luer connector	Yes	Yes
Two (2) eyelet holes near tip	Yes	Yes
Radiopaque line entire length of tubing	Yes	Yes
Markings along the length of the tubing	Yes	Yes
Materials		
Tubing and Connector – PVC with no DEHP	Yes	Yes
Packaging		
Sterile	Yes	Yes
Performance		
None under Section 514	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicate – ProMedic Infant Feeding Tube – K020005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2005

Mr. Paul Dryden
President
ProMedic, Inc.
6329 W. Waterview Court
MCCORDSVILLE IN 46055

Re: K052903
Trade/Device Name: Infant Feeding Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: October 13, 2005
Received: October 14, 2005

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K052903 (To be assigned)

Device Name: Infant Feeding Tube

Indications for Use: The Infant Feeding tube is intended to be placed into the stomach to permit the introduction of fluids as directed by the physician. Intended for nasogastric or orogastric placement. Limited to < 30 day placement. Not intended for transpyloric placement.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K 052903