K072756
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## Non-Confidential Summary of Safety and Effectiveness


26-Sept-07

ProMedic, Inc.
3460 Pointe Creek Court #102.
Bonita Springs, FL 34134

Tel (239) 498-2155
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**Official Contact:** Paul Dryden

DEC 1 9 2007

**Proprietary or Trade Name:** Infant Feeding Tube with Non-IV fittings

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

**Classification Name:** Tubes, Gastrointestinal (and Accessories)

**Predicate Devices:** ProMedic - Infant Feeding Tubes – K052903

**Device Description:**
The proposed modification to Infant Feeding Tube is to change the fittings from a standard slip fit luer to a non-IV (luer) size connector. The feeding tubes are 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. We will offer a non-sterile syringe with the appropriate mating, non-IV connector as part of a kit.

**Indications for Use:**
A non-IV connector for use with Infant Feeding tubes that are 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.

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

**Comparison to Predicate Devices:**

| **Attribute** | **Proposed device with modification** | **Predicate ProMedic Infant Feeding Tube – K052903** |
|---|---|---|
| Indications<br>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. |
| Type of placement | Nasogastric or orogastric<br>Not for transpyloric placement. | Nasogastric or orogastric<br>Not for transpyloric placement. |
| Length of placement | < 30 days | < 30 days |
| Intended for single patient use | Yes | Yes |
| Prescription | Yes | Yes |

## Non-Confidential Summary of Safety and Effectiveness



| Attribute | Proposed device with modification | Predicate ProMedic Infant Feeding Tube – K052903 |
|---|---|---|
| Intended population | Infants / pediatrics | Infants / pediatrics |
| Intended Environment of Use | Hospital, home or environments where placement of a Feeding tube is required. | Hospital, home or environments where placement of a Feeding tube is required. |
| **Design Features** | | |
| Provided in various diameters from 4 - 12 Fr | 5, 6, 8 Fr | 5, 6, 8 Fr |
| **Connector** | **Non-IV slip fit female connection**<br>**Must be used with an appropriate syringe with non-IV male mating connector** | **Standard slip fit female luer** |
| 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 | Yes | Yes |
| **Packaging** | | |
| Sterile | Yes<br>Syringe offered non-sterile | 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 – K052903.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

Mr. Paul Dryden
President
ProMedic, Inc.
3460 Pointe Creek Court, #102
BONITA SPRINGS FL 34134

Re: K072756
Trade/Device Name: Feeding tube adapter
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: September 26, 2007
Received: September 27, 2007

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

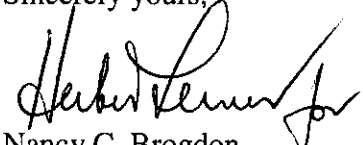
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,



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

K072756

## Indications for Use Statement



**510(k) Number:** _____ (To be assigned)

**Device Name:** Feeding tube adapter

**Indications for Use:**

A non-IV connector for use with Infant Feeding tubes that are 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072756