K970849

Medical Infusion Technologies, Inc
6576 East Quaker Stree
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AUG 15 1997

# Premarket Notification [510(k)] Summary

as required by section 807.92(c)

Preparation Date: March 4, 1997

Per requirements of this section, the letter head contains address, phone, and fax numbers of the submitter, Mr John McNeirney, Vice President.

Trade name - "Enteral Nutrition"
Common name - is Enteral Feeding Bag and accessories
Classification name - Gastrointestinal tube and accessories (per CFR 876.5980(a))

The Enteral Nutrition device is equivalent to the RPI Enteral Feeding Bag, manufactured by Ridge Products, Inc., carrying 510(k) number K902641.

The device is a common enteral feeding bag.

The device will be used for dispensing liquid nutrients and medication under a doctors prescription.

The device will be identical to units on the market with the exception of our private label and per HHS Publication FDA 95-4158 "Premarket Notification 510(k), Regulatory Requirements for Medical Devices", page 3-7 "Clinical data is not needed for most devices cleared by the 510(k) process."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Mr. John McNeirney
Vice President
Medical Infusion Technology, Inc.
6576 East Quaker Street
Orchard Park, New York 14127-2593

Re: K970849
Enact™ Enteral Feeding Bag
Dated: June 13, 1997
Received: June 17, 1997
Regulatory Class: II
21 CFR §876.5980/Product Code: 78 KNT

Dear Mr. McNeirney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## "Indication For Use"

510(k) Number : **K970849**

This product must be used only under a doctor's prescription. Its indications for use are various medical situations wherein the patient is nourished by an appropriate formula by means of a tube passed into the stomach from the nasal passage. It is used for patients who for some reason are unwilling or unable to masticate or swallow food. The product is not for intravenous feeding.

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970849

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____