



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sanford W. Bigelow, Ph.D.  
Director, Medical Nutritional  
Regulatory Affairs  
Ross Products, Abbott Laboratories  
625 Cleveland Avenue  
Columbus, Ohio 43215

JAN 26 1998

Re: K972437  
Flexflo Magnetically Guided Enteral Feeding Tube  
Regulatory Class: II  
Product Code: 78 FPD  
21 CFR 876.5980  
Dated: October 31, 1997  
Received: November 4, 1997

Dear Dr. Bigelow:

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. 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 (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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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,

*Robert D. Nathing*

*for*

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

**VIII. INDICATIONS FOR USE**

The Flexiflo Magnetically Guided Enteral Feeding Tube system is intended for direct placement in the small bowel. The tube functions as a conduit to facilitate enteral feeding, and may be used in pediatric, adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with a functioning gut who require short- to moderate-term feeding support, such as post-trauma patients, post-surgical patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists, or may result, secondary to an underlying disease or condition.

The external steering magnet functions as a guidance tool to assist in the safe, rapid placement of the feeding tube into the small bowel.

The pH tape is used to measure the acidity or alkalinity of gastric and small bowel fluids that are obtained during initial placement.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Natting /  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K972437

Prescription Use  OR Over-The-Counter Use

(Per 21 CFR 801.109)