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 Division
Abbott Laboratories
625 Cleveland Avenue
Columbus, Ohio 43215-1724

NOV - 7 1997

Re: K962554
Flexiflo® Low-Profile Balloon Gastrostomy
Tube Kit and Accessories
Dated: September 29, 1997
Received: September 30, 1997
Regulatory class: II
21 CFR §876.5980/Product code: 78 KNT

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) 594-4616. 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 R Nathan /

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 Low-Profile Balloon Gastrostomy tube is indicated for use as a replacement tube in an established stoma tract for pediatric, adult and elderly patients who cannot consume an adequate diet orally. Gastrostomy feeding may be indicated for patients with a functioning gut who require long-term feeding support. This includes patients in whom malnutrition already exists, or may result, secondary to neurologic diseases resulting in an abnormality in swallowing; tumors of the head, neck or esophagus; or upper airway diseases or oropharyngeal trauma resulting in an abnormality in swallowing. Some patients requiring chronic use of supplemental fluids are candidates for gastrostomy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Sattler

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K962554

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)