JUL 26 1999

Novartis Nutrition Corporation
Technical Center
1541 Park Place Boulevard
St. Louis Park MN 55416-1514

NOVARTIS

510(k) SUMMARY

COMPAT®JEJUNOSTOMY FEEDING TUBE KIT

SUBMITTER: Robert J. Lang
Novartis Nutrition Corporation
P.O. Box 370
Minneapolis, MN 55440
TEL: (612) 591-2950
FAX: (612) 591-2941

CONTACT PERSON: Sharon Martin

DATE PREPARED: May 5, 1999

NAME OF DEVICE:

TRADE NAME: Novartis Nutrition COMPAT® Jejunostomy Tube Kit

COMMON NAME: Jejunostomy Tube Kit

CLASSIFICATION NAME: Gastrointestinal Tubes and Accessories
(per 21CFR 876.5980)

PREDICATE DEVICE: Medical Innovations Corp. MIC Jejunostomy Tube #300-014
510(k) Number: K880767

DESCRIPTION: The Jejunostomy Tube is a surgically placed small bowel feeding access port intended for single patient use.

INTENDED USE: The device delivers enteral solutions and medications directly into the small intestine.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The COMPAT® Jejunostomy Tube Kit has the same intended use as the MIC Jejunostomy Tube. Principle differences include:

- Length of 50cm compared to 30cm
- Solid radiopaque silicone compared to clear with stripe
- Exit ports located at the side and open-end of tube compared to open-end only
- No "wings" or suture cuff compared to 2 soft "wings" and a Dacron cuff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 1999

Mr. Robert J. Lang
Director of Quality Operations
Novartis Nutrition Corporation
5320 West 23rd Street
PO Box 370
Minneapolis, MN 55440

Re: K991668
COMPAT® Jejunostomy Tube Kit
Dated: May 5, 1999
Received: May 14, 1999
Regulatory Class: II
21 CFR §876.5980/Procode 78 KNT

Dear Mr. Lang:

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 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. 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 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, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K991668

DEVICE NAME: COMPAT Jejunostomy Tube Kit

INDICATIONS FOR USE:

The Novartis Nutrition COMPAT Jejunostomy Tube is a surgically placed small bowel feeding access port intended for single patient use. The device delivers enteral solutions and medications directly into the small intestine. When direct access to the small bowel lumen is necessary, the tube may be placed, and positioned within the small bowel using an appropriate technique. It may be permanently fixed to the skin of the outer abdomen using the external retainer provided and suture, or another appropriate fixation technique.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991668