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K981323
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APPENDIX F

510(K) SUMMARY

Submitter Name:

Novartis Nutrition Corporation
PO Box 370
Minneapolis, MN 55440

Robert J. Lang
Director of Quality Operations
612-591-2950

March 30th, 1998

Device Name :

Classification Name:	Gastrointestinal Tube and Accessories (21 CFR 876.5980)
Common/Usual Name:	Replacement Gastrostomy Tube Kit and Accessories.
Trade Name:	Novartis Nutrition COMPAT MINI-G Replacement Gastrostomy Tube Kit

Identification of the Legally Marketed Device

The current legally marketed device is the Novartis Nutrition (Sandoz Nutrition)/Superior Healthcare Flow-Thru Replacement Balloon Gastrostomy Tube Kits. This line of replacement gastrostomy tubes is currently marketed under K885339.

Description of the device that is the subject of this 510(K).

This 510(k) is for the Novartis Nutrition COMPAT MINI-G Replacement Gastrostomy Tube Kits.

The Novartis Nutrition COMPAT MINI-G Replacement Gastrostomy Tube kit is a Class II medical device and is intended for use as an enteral feeding tube to deliver feeding formula and/or medications to the stomach, as well as providing the ability to decompress and drain the stomach.

Statement of intended use of the device.

The Novartis Nutrition COMPAT Mini-G Feeding Tube Kit provides for the delivery of enteral formula through an externally minimized feeding tube. This replacement tube is used when there exists an established, well healed and mature stoma tract communicating between the stomach and external body surface. Externally minimized or low profile feeding devices are used to minimize the exposure of the tube outside of the patient's body and to provide an improved body image to the patient by concealing the feeding device under the clothing

Summary of technological characteristics in comparison to those of the predicate device.

The Novartis COMPAT MINI-G Tube affords the same intended use of providing the ability to feed into the stomach or drain/decompress the stomach as with the SE device.

The MINI-G is placed into an existing mature stoma tract. With lubricant applied, the tip of the MINI-G Tube may be inserted through the stoma tract and into the stomach where the balloon can be inflated to retain the tube's gastric position. This is the identical procedure used to place the SE device.

The radiopaque marker in the tip of the MINI-G Tube may be located by radiological techniques to confirm the it is retained with in the gastric space. This is the same for the SE device.

The same balloon gastric retention means is used with both the Novartis COMPAT MINI-G Tube and the SE device. Inflation of the balloon gastric retainer of the Novartis COMPAT MINI-G Tube and that of the SE device requires the infusion of water from a syringe through a safety valve. The valve of the MINI-G Tube is smaller and constructed of a single piece of silicone material bonded inside the inflation arm, while for the SE device a larger plastic valve is attached to the outside of the inflation arm. Both require syringes to activate; however, the Novartis COMPAT MINI-G Tube also requires the use of a blunt needle to temporarily penetrate the valve opening.

Inflation volumes are the same in both the Novartis COMPAT MINI-G Tube and the SE device, ranging from 5 cc to 15 cc of water.

The external (skin surface) retaining method of the Novartis COMPAT MINI-G Tube is the same as that for the SE device and consists of a friction-fit silicone oval or disk which slides over the length of the tubes shaft and remains in position by virtue of the friction on the shaft. In addition, the MINI-G Tube external retainer has a capture collar capable of holding the tube near to the patient's skin and assisting in achieving immobility of the tube. The positioning of the MINI-G Tube shaft in the collar is facilitated by a predisposed curvature molded into the tube shaft.

The Novartis COMPAT MINI-G Tube has a removable plug attached by a strap to its feeding port the same as does the SE Device. In addition, however, the MINI-G Tube contains an anti-reflux, one-way valve situated in the feed port to which the plug engages. This valve prevents backflow (reflux) of gastric contents when the plug is opened and

before the feeding connector can be attached. This valve is essentially the same as that described in K924308 (Sandoz Nutrition Gastroport II).

Decompression of the stomach is basically the same for the Novartis MINI-G Tube and the SE device as the drainage is accomplished through the same port as feeding when the plug/cap is removed. However, with the Novartis COMPAT MINI-G Tube the one-way anti-reflux valve must also be opened before decompression can occur. This is accomplished with the Decompression Tube, the tip of which when inserted into the feed port opens the valve and allows drainage and decompression to occur. This is the same method and device as described in K924308 (Sandoz Nutrition Gastroport II).

Conclusions Drawn that demonstrate that the device is safe, as effective and performs as well as the legally marketed device.

Novartis Nutrition believes that the changes described in this submission do not negatively affect the safety or effectiveness of this product.

Indications for Use:

The Novartis Nutrition COMPAT Mini-G Feeding Tube Kit provides for the delivery of enteral formula through an externally minimized feeding tube. This replacement tube is used when there exists an established, well healed and mature stoma tract communicating between the stomach and external body surface. Externally minimized or low profile feeding devices are used to minimize the exposure of the tube outside of the patient's body and to provide an improved body image to the patient by concealing the feeding device under the clothing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 1998

Mr. Robert J. Lang
Director of Quality Operations
NOVARTIS Nutrition Corporation
Technical Center
1541 Park Place Blvd.
St. Louis Park, Minnesota 55416-1514

Re: K981323
COMPAT® MINI-G™ Gastrostomy Feeding Device
Regulatory Class: II
21 CFR 876.5980
Product Code: 78 KNT
Dated: August 17, 1998
Received: August 20, 1998

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. 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

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/dsma/dsmamain.html".

Sincerely yours,

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

K981323

INDICATIONS FOR USE

510(K) Number (if known)

Device Name: COMPAT® MINI-G™ REPLACEMENT GASTROSTOMY TUBE KIT

Indications for Use:

The Novartis Nutrition COMPAT Mini-G Feeding Tube Kit provides for the delivery of enteral formula through an externally minimized feeding tube. This replacement tube is used when there exists an established, well healed and mature stoma tract communicating between the stomach and external body surface. Externally minimized or low profile feeding devices are used to minimize the exposure of the tube outside of the patient's body and to provide an improved body image to the patient by concealing the feeding device under the clothing.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981323/S001

Prescription Use ✓
(Per 21 CFR 801.109)