

K07491  
1 of 4

**510(k) Summary**  
(per 21 CFR 807.87(h))

JUL 23 2007

Common/Usual Name: **Gastrostomy/Jejunostomy Feeding Tube Kit**

Product Trade Name: **COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube Kit, Model #088000**

Classification Name: **Tubes, Gastrointestinal (and Accessories)**  
**Class II per 21 CFR §876.5980**  
**Product Code KNT**

Predicate Device: **Novartis Item 088000, COMPAT® Surgical Gastrojejunostomy Feeding Tube Kit, (K965087)**

Manufacturer: **Novartis Nutrition Corporation**  
**1541 Park Place Blvd**  
**St. Louis Park, MN 55416**

Establishment Registration: **2110851**

Contact: **Sue Fidler,**  
**Manager, Regulatory Affairs NA**  
**Telephone: 952-848-6328 / Fax: 952-848-6319**  
**Email: [susan.fidler@novartis.com](mailto:susan.fidler@novartis.com)**

Performance Standards: **No performance standards have been developed under section 514 for this device.**

Date Prepared: **April 21, 2006**

**Device Description:**

The Novartis Nutrition COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube is packaged in a sterile kit. It is designed for easy intra-operative placement and facilitates immediate postoperative feeding into the jejunum. The two-tube system allows for easy placement and replacement in the event of a jejunal tube clog. The large gastrostomy tube provides access to the stomach for decompression and

drainage. The system's jejunal feeding tube is easy to place intra-operatively through the gastrostomy tube into the small bowel using the innovative balloon tipped stylet provided in the kit.

The major components of the kit include:

- 28 FR Silicone Gastrostomy Tube
- 12 FR Polyurethane Jejunal Feeding Tube with Double Lumen FEED/DRAIN adapter and radiopaque, flow-through tip
- Preassembled disposable balloon tipped stylet<sup>1</sup>

The COMPAT administration set contains or attaches to the formula reservoir/container and provides the conduit to deliver the feeding solution to the patient's feeding tube via a feeding pump. The patient's feeding tube may be a variety of tubes including, but not limited to, a nasogastric tube, a gastrostomy tube, or a jejunostomy tube. The administration set attaches to the patient's feeding tube to provide the formula or feeding solution required.

#### **Statement of Intended Use:**

The COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube Kit is intended for use as a surgically placed gastrostomy tube intended to deliver enteral feeding formulas directly into the small bowel (jejunum). The COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube is intended for use with patients who require enteral feeding. Indications for such medical and post-surgical treatments may include surgical problems, prolonged artificial ventilation, central nervous system trauma, and others. The placement of the device in patients is accomplished surgically using standard surgical techniques. This method is used to enhance the absorption of nutrients and minimize the risks of gastric feeding including gastric reflux and aspiration.

The COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube also provides for the evacuation of gastric contents through the gastrostomy tube while simultaneously feeding directly into the small bowel with the jejunal feeding tube. This device is for use under medical supervision only.

#### **Indications for Use:**

The COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube Kit provides for the delivery of enteral formula through a surgically placed Gastrostomy/Jejunostomy feeding tube. Jejunal feeding is used when patients require feeding past the stomach directly

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<sup>1</sup> The balloon on the disposable stylet is made from natural rubber latex. The stylet is removed after placement.

into the jejunum. This method is used to enhance the absorption of nutrients and minimize the risks of gastric feeding including gastric reflux and aspiration.

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

**1. Intestinal feeding and gastric drainage.**

The COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube Kit provides the same ability as the comparative substantially equivalent device for delivery of formula and medications to the small intestine (through "FEED" port) while allowing simultaneous gastric drainage (through "DRAIN" port) via the gastrostomy tube. The COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube also provides for the evacuation of gastric contents through the gastrostomy tube while simultaneously feeding directly into the small bowel with the jejunal feeding tube.

**2. Placement techniques and confirmation methods.**

Initial placement of the COMPAT<sup>®</sup> Surgical Gastrostomy/Jejunostomy Feeding Tube may be accomplished surgically, as with the predicate substantially equivalent device through a laparotomy midline incision and Stamm (gastrostomy) technique. The jejunal feeding tube can be placed in a similar fashion to that of the substantially equivalent device in that the tube is led through the lumen of the gastrostomy tube into the stomach, then grasped at its tip and manipulated through the gastric pylorus into the small intestine.

This manual manipulation into the bowel is assisted by the presence of the bolus tip on the jejunal tube and by a removable stylet. The inflation of the cuff provides an additional (temporary) feature for grasping and directing the jejunal tube tip.

Both the substantially equivalent and this device contain a Y-port at the connector end of the Jejunal Feeding tube, which may be pressed into the lumen of the Gastrostomy tube to complete the placement and allow for gastric drainage through the gastrostomy tube. The Gastrostomy/Jejunostomy tube combination may be immobilized using the external retainer and the abdomen may be closed in the standard fashion.

Confirmation of placement of both tubes may be accomplished using x-ray or fluoroscopic techniques.

**3. Tube and Stylet Construction.**

The materials of construction of the Gastrostomy and Jejunostomy tubes are identical to that of the substantially equivalent device. The only difference is the orientation of the radiopaque material in the jejunal tubing. The tubing of the

substantially equivalent device contained 20% barium sulfate in a stripe configuration, whereas the modified tubing is solid filled 20% barium sulfate. The content of the barium sulfate contained in the tube has not changed from that of the substantially equivalent device.

**Summary of Non-Clinical Testing:**

No additional non-clinical testing of this product for this use was conducted.

**Summary of Clinical Testing:**

No additional clinical evaluations of this product for this use have been conducted.

**Predicate Devices:**

The predicate device of the Novartis Nutrition Corporation COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube Kit item number 088000, as modified, is the Sandoz Nutrition COMPAT® Surgical Gastro/Jejunostomy Feeding Tube Kit, (K965087). The company name has been changed from Sandoz Nutrition to Novartis Nutrition Corporation.

**Conclusions:**

Novartis Nutrition Corporation COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube Kit item number 088000, as modified, is substantially equivalent to Sandoz Nutrition COMPAT® Surgical Gastro/Jejunostomy Feeding Tube Kit, (K965087).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Novartis Nutrition Corporation  
c/o Ms. Laura Danielson  
Program Manager  
TÜV SÜD America, Inc.  
1775 Old Highway 8 NW, Ste. 104  
NEW BRIGHTON MN 55112-1891

JUL 23 2007

Re: K071191  
Trade/Device Name: COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube Kit  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: FPD  
Dated: July 9, 2007  
Received: July 10, 2007

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

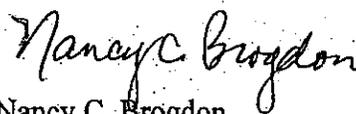
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

Current 510(k) Number: K071191

Device Name: COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube Kit

### Indications for Use:

The COMPAT® Surgical Gastrostomy/Jejunostomy Feeding Tube Kit provides for the delivery of enteral formula through a surgically placed Gastrostomy/Jejunostomy feeding tube. Jejunal feeding is used when patients require feeding past the stomach directly into the jejunum. This method is used to enhance the absorption of nutrients and minimize the risks of gastric feeding including gastric reflux and aspiration.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K071191