K961664

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510(K) SUMMARY

Submitter Name:

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Device Name :

Classification Name:	Gastrointestinal Tube and Accessories (21 CFR 876.5980)
Common/Usual Name:	Nasojeunal Feeding Tube with or without Gastric Drainage.
Trade Name:	Sandoz Nutrition COMPAT Nasojejunal Feeding Tube.

Identification of the Legally Marketed Device

The #082302 NASOJEJUNAL FEEDING TUBE WITH GASTRIC DRAINAGE AND the #082304 NASOJEJUNAL FEEDING TUBE FOR SURGICAL PLACEMENT are Substantially Equivalent (SE) to the Sandoz Nutrition #082301 Nasojejunal Feeding Tube With Gastric Drainage and the Sandoz Nutrition #082303 Nasojejunal Feeding Tube legally marketed under
510(k): K913407/B

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

A Nasojejunal Feeding Tube with or without Gastric Drainage.

Statement of intended use of the device.

The Sandoz Nutrition #082302 NFG Tube is intended for use with patients who require both enteral feeding and gastric suction simultaneously. The Sandoz Nutrition #082304 NF Tube is intended for use with patients who require only 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 can be accomplished intraoperatively at laparotomy using standard surgical techniques.

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

The tubes of this submission and the predicate device are both intended to provide means for delivering enteral formula to the intestine (i.e., post pylorically). The #082302 tube, also provide the means for gastric evacuation or drainage which is the same intended use of the predicate device #082301

The Placement technique and confirmation methods differ slightly from the predicate device. The devices in this submission are designed to facilitate placement into a patient intraoperatively using standard surgical techniques at laparotomy. The predicate devices may be placed using fluoroscopic and endoscopic guidewire techniques; however, these tubes can also be placed surgically, depending on physician preference.

Confirmation of placement position for all of the tubes above may be performed using radiographic techniques since certain location features are radiopaque (i.e., Bolus Tip, Grasping Rings, 9/18 FR Gastric Bushing, and tubing stripe).

The feeding tubes of this submission are nearly identical to the currently marketed tubes with the exception that **grasping rings and bolus tips** are added to the 9 French feeding portion of the tubes. The grasping rings located at the distal end of the tube are designed to assist in surgical palpation on manipulation of the tube tip during placement of the tube.

The feeding tubes and the stylets/stiffener of this submission are made of identical materials to those used in the currently marketed SE devices. The lengths, diameters, gastric suction holes and Y connectors of the devices of this submission are identical to those of the currently marketed SE devices.

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

Sandoz Nutrition believes that the changes described in this submission do not negatively affect the safety or effectiveness of the product. The material and bonding method for the grasping rings and bolus tip are identical to those used in the SE device. Furthermore, there have been no complaints with respect to the materials in the 5 years that the SE device has been marketed.