



Food and Drug Administration
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August 9, 2016

Syncro Medical Innovations, Inc.
% William G. McLain
Consultant
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, PA 17540

Re: K160787
Trade/Device Name: Gabriel Feeding Tube with Balloon
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: June 24, 2016
Received: June 28, 2016

Dear William McLain:

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. However, you are responsible to determine that the medical devices you use as components in the Gabriel Feeding Tube with Balloon 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/tray. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

In addition, we have determined that your device kit contains Benzocaine Gel 20% which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Douglas Silverstein -S
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Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160787

Device Name

Gabriel Feeding Tube with Balloon

Indications for Use (Describe)

The Gabriel Feeding Tube with balloon functions as a conduit to facilitate enteral feeding, and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support, such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

A 510(K) Summary

A.1 Submission Correspondent and Owner

Submission Correspondent

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A.2 Date Summary Prepared

August 9, 2016

A.3 Device Trade Name

Gabriel Feeding Tube with Balloon

A.4 Device common name

Feeding Tube

A.5 Device classification name

Tube, Feeding. 78 KNT at 21 CFR Part 876.5980

A.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

Predicate Device

Syncro Blue Tube Magnetically Guided Enteral Feeding Tube (K110005)

Reference Device

Rusch Miller-Abbott Tube (K010797).

A.7 Description Of The Device

The Gabriel Feeding Tube with Balloon serves as a conduit through which enteral feeding solutions are directly infused into the patients small bowel. During placement of the tube, a lubricant and or numbing gel is applied to the nostril.

For the version of the tube with stylet with magnetic tips, an external magnet is used to assist the physician in placing the tube into the small bowel. Like the predicate device, the modified device has a stylet with a reed switch positioned near its distal tip. The reed switch is connected by wires to an external LED/battery pack that lights in response to the presence of the external steering magnet. The reed switch is encased in a lead-free glass tube and metal shield and is attached to the distal end of the stylet. The wires used to connect the distal reed switch to the LED are polyurethane insulated copper and are wrapped around the core of the stylet and contained inside the outer PTFE layer, thus keeping it out of the fluid path. The distal tip of the stylet contains magnets which are attracted to the steering magnet. The inflated feeding tube balloon allows peristalsis to advance the feeding tube distally.

For the version of the tube with the non-magnetic stylet, the tube is manually inserted by the physician. The stylet, is non patient contacting, made out of seven braided filaments 305 stainless steel wire and is 3 cm shorter than the feeding tube.

The stylet is removed and tube taped at the nose and placement verified by pH paper and abdominal x-ray. Like the predicate device, the modified Gabriel Feeding Tube with Balloon has a stylet. The inflated feeding tube balloon allows peristalsis to advance the feeding tube distally.

The external tube is extruded over reinforcing monofilament stainless steel wire that prevents occlusion by kinking. The outer patient contacting layer is made from DEHP-free PVC.

A.8 Intended Use

The Gabriel Feeding Tube with balloon functions as a conduit to facilitate enteral feeding, and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support, such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.

A.9 Technological Characteristics

The proposed device has the same technological characteristics as the predicate device. Specifically, both feed tubes function by providing a conduit for enteral feeding. For the magnetic version of the device, the insertion methods are identical to the Syncro (K110005) predicate device in that they utilize identical techniques for placing the tube. Both the proposed magnetic and non-magnetic devices have similar technological characteristics related to the reference device Rusch Miller-Abbott Tube (K010797) in that the balloon facilitates placement using the GI tract's peristaltic action.

A.10 Non-Clinical Testing

Tests were performed to demonstrate substantial equivalence in the following areas:

- Non-Magnetic Stylet Hub Pull Test
- Flexibility and Pushability Test
- Comparison Volumetric Flow Rate Test
- Connection Testing
- Aspiration through the feeding tube test to document that gastric fluid can be aspirated through 8 Fr, 10 Fr, and 12 Fr Gabriel feeding tube with balloon
- Gabriel Feeding Tube with Balloon leakage test after filling tube balloon with colored water
- Gabriel Feeding Tube with Balloon System liquid flow and leakage test
- Gabriel Feeding Tube with Balloon shaft tensile test
- Gabriel Feeding Tube with Balloon Shaft to Y Connector Tensile Test
- Gabriel Feeding Tube with Balloon Shaft to Balloon inflation port Tensile Test

A.11 Biocompatibility

Materials were tested for cytotoxicity, sensitization, irritation, acute and sub-chronic toxicity. The materials were confirmed to be biocompatible.

A.12 Clinical Testing

No clinical testing was performed in association with this submission.

A.13 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.