November 15, 2019

Syncro Medical Innovations, Inc.
Sabry Gabriel, MD
President
515 Mulberry St., Suite 200
Macon, GA 31201-6308

Re: K191784
Trade/Device Name: Gabriel Feeding Tube with Balloon, and EnFit Connector
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: October 4, 2019
Received: October 8, 2019

Dear Sabry Gabriel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the Gabriel Feeding Tube with Balloon, and enfit connector 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Shani P. Haugen, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191784

Device Name
Gabriel Feeding® Tube with Balloon, and ENFit Connnector

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket Notification 510(k) Summary:

5.1 Submitter Information

Company:	Sabry Gabriel MD, President Syncro Medical Innovations, Inc. 515 Mulberry St Suite 200 Macon, GA 31201-6308 USA Telephone: 478-335-8311 Fax: 716-809-3504 sabrygabriel@syncromedical.com
Contact:	Sabry Gabriel MD, President Syncro Medical Innovations, Inc. 515 Mulberry St Suite 200 Macon, GA 31201-6308 USA Telephone: 478-335-8311 Fax: 716-809-3504 sabrygabriel@syncromedical.com
Date Summary Prepared:	November 14, 2019

5.2 Name of the Device

Trade Name:	Gabriel® Feeding Tube with Balloon, and EnFit Connector
Common Name:	Nasoenteral Feeding Tube with Balloon
Classification Name:	Gastrointestinal tubes and accessories
Review Panel:	Gastroenterology & Urology (GU)
Regulation:	876.5980
Class:	Class II
Product Code:	PIF

5.3 Equivalence Claimed to Predicate Device

The Gabriel® Feeding Tube with Balloon, and EnFit Connector is equivalent to the Gabriel® Feeding Tube with Balloon (K160787), manufactured by SYNCRO MEDICAL INNOVATIONS, INC.

5.4 Basis for substantial Equivalence

The device has identical indications for use, intended population, materials used and functionality as the predicate device "Gabriel Feeding Tube with Balloon" (K160787), cleared on August 9, 2016.

The device label is changed from MR unsafe to MR conditional based on supporting test results.

The device proximal Y shaped catheter tip connector is replaced with a rigid male EnFit connector to mitigate misconnection risk without changing principal function, indication for use, intended use or intended patient population.

Three previously cleared items are added to the convenience kit to facilitate bedside insertion procedure. None of the changes or added items to the convenience kit negatively impact the device intended function or raise a new safety concern.

The three items added to the convenience kit are: (A) A 3-way EnFit stopcock valve (K915171), (B) Silk thread (K931271) that can be optionally used in the updated insertion technique, (C) CO2 sampling line (K181981) that can facilitate quick detection of misplacement in the airway in addition to observing pulse oximetry as in the predicate device. The feeding tube is a single use, finished device and sold for use by prescription only. It is provided non-sterile in three different sizes; 12 Fr, 10 Fr and 8 Fr. All three sizes are preassembled with nonmagnetic stylets.

5.5 Legally Marketed Device To Which The Device is Substantially Equivalent (Predicate Device):

Gabriel Feeding Tube with Balloon (K160787)

5.6 Description Of The Device and Placement Procedure:

The Gabriel Feeding Tube with Balloon serves as conduit through which enteral feeding solutions are directly infused into patients small bowel. The tube has two distal end openings, one distal end balloon, one proximal end pilot balloon that indicates the status of the inflation of the distal end balloon and a proximal end EnFit connector that replaced our Y shaped catheter tip connector of the predicate device. The tube shaft is lined by a monofilament spiral wire to prevent occlusion from kinking. A braided 7 strands stainless steel stiffening central stylet prevents coiling in the mouth during insertion and provides column strength to facilitate placement into the stomach.The tube patient contacting material is made from DEHP-free PVC. Size 12 Fr tube is 130 cm long. During insertion of the tube, a lubricant and or a numbing gel is applied to one nostril. A silk thread is looped through the tube two distal openings. It can be optionally used to deflect the tube downwards towards the oropharynx, then discarded. A CO2 sampling line is connected to the tube proximal end to faciltate detection of feeding tube misplacement into the trachea, then discarded at the end of the insertion procedure. At 18 cm mark patient, if awake, is asked to swallow. At 30 cm depth mark, the feeding tube balloon and pilot balloon are inflated with 6 ml of air. Observing fluctuation in CO2 sampling wave or a drop in pulse oximetry by 5 or more points is an indication of tube misplacement into the trachea. This can be corrected by deflating the balloon immediately, withdrawal to 18 cm depth mark then reinsertion. Once esophageal placement is established, the tube with balloon inflated is advanced to the stomach. At 70 cm mark the stylet is partially removed as the tube is advanced to the 100 cm mark and taped at the nose. The stylet and CO2 sampling lines are removed and x-ray is obtained to confirm gastric or duodenal placement. The inflated tube distal end balloon allows peristalsis to advance the feeding tube distally. The balloon is deflated after 2 days, or before removal of the tube.

5.7 Indication For 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.

5.8 Technological Characteristics

The proposed device(K191784) has the same technological characteristics as the predicate device (K160787). Specifically, both feeding tubes function as conduit for enteral feeding.

Both the proposed and predicate feeding tubes are propelled distally by effect of peristalsis on the tube distal end balloon.

Both the proposed and predicate feeding tubes utilize inflation of the distal end balloon at 30 cm mark to detect airway misplacement by observing changes in pulse oximetry. In addition, the proposed device utilizes a previously cleared CO2 sampling line for additional detection of airway misplacement. The CO2 sampling line is connected to the proximal end of the feeding tube outside the patient and is discarded at the end of the insertion procedure.

Both the proposed and predicate feeding tubes have a stainless steel wire-enforced wall to prevent occlusion by kinking.

Both the proposed and predicate feeding tubes have a central stainless steel non patient contacting stiffening stylet.

5.9 Non-clinical testing

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

Feeding formula flow rate test using model with EnFit connector and compared to predicate device with catheter tip connector (pass)

Tube shaft to male EnFit connector tensile test (pass)

Stylet to stylet hub tensile test (pass)

48 Months shelf life test on the device with catheter tip connector (pass)

Tests conducted on the EnFit connector:

Leakage by pressure decay test (pass)

Positive pressure liquid leakage test (pass)

Stress cracking test (pass)

Resistance to separation from Axial load test (pass)

Resistance to separation from unscrewing test (pass)

Thread overriding resistance test (pass)

Disconnection by unscrewing test (pass)

Dimensional verification of EnFit connector (pass)

EnFit connector material elasticity modulus above 700 MPa (pass)

MR safety test (MR conditional)

5.10 Biocompatibility

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

5.11 Clinical Testing

No clinical testing was performed in association with this submission.

5.1: Device Comparison Table

Device Name	**Proposed Device: Gabriel® Feeding Tube with Balloon, and EnFit Connector (K191784).**	**Predicate Device: Gabriel Feeding Tube with Balloon (K160787).**
Intended Use	A nasoenteric conduit used to facilitate enteral feeding. The device is intended to be inserted during bedside procedures.	A nasoenteric conduit used to facilitate enteral feeding. The device is intended to be inserted during bedside procedures.
Indication for 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,	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.	high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.
Patient Contacting Materials	-Tube shaft outside: PVC Tekni-Plex Technologies (Suzhou) Co., Ltd - Grade or Model 7811 - Tube balloon: PVC Tekni-Plex Technologies (Suzhou) Co., Ltd Grade or Model 6511 - Tube inner surface: PVC Tekni-Plex Technologies (Suzhou) Co., Ltd - Grade or Model 7811 with a spiral 316 stainless steel coil	-Tube shaft outside: PVC Tekni-Plex Technologies (Suzhou) Co., Ltd - Grade or Model 7811 - Tube balloon: PVC Tekni-Plex Technologies (Suzhou) Co., Ltd Grade or Model 6511 - Tube inner surface: PVC Tekni-Plex Technologies (Suzhou) Co., Ltd - Grade or Model 7811 with a spiral 316 stainless steel coil
Dimensions/Sizes	GFTB 512 with EnFit connector, 12 Fr x 130 cm, Non-Magnetic Stylet Design, 1.2 mm Stylet Diameter, 3 mL Balloon GFTB 510 with EnFit connector, 10 Fr X 100 cm, Non-Magnetic Stylet Design, 1.2 mm Stylet Diameter, 3 mL Balloon; GFTB 508 with EnFit Connector, 8 Fr x 80 cm, Non-Magnetic Stylet Design, 1.0 mm Stylet Diameter, 1 mL Balloon;	GFBT 412, 12 Fr x 130 cm, Magnetic and Non-Magnetic Stylet Design, 1.2 mm Stylet Diameter, 3 mL Balloon GFTB 410, 10 Fr x 130 cm, Magnetic and Non-Magnetic Stylet Design, 1.2 mm Stylet Diameter, 3 mL Balloon GFTB 408, 8 Fr x 100 cm, Magnetic and Non-Magnetic Stylet Design, 1.0 mm Stylet Diameter, 1 mL Balloon
Provided Accessories (all received premarket notification (K)number, or exempt)	Numbing gel, lubricant gel, cotton swab, luer lock syringe, skin adhesive, securing tape, silk suture thread, EnFit 3-way stopcock valve (k)915171 and CO2 sampling line (k)181981	Numbing gel, lubricant gel, pH paper, cotton swab, luer lock syringe, skin adhesive, and securing tape
Shelf Life/Expiration	Shelf life increased to 48 months after appropriate tests met acceptance criteria.	18 months
MR safety	MR Conditional based on test result	MR Unsafe due to lack of testing
Proximal end connector	Rigid male EnFit with elastic modulus above 700 MPa	Flexible Y shaped catheter tip port

Connectivity	Directly to EnFit feeding line or through 3-way EnFit stopcock valves (k)915171	Requires adapter with EnFit feeding line or Lopez 3-way valve with catheter tip port
Flushing and administration of medicine	Using EnFit syringe	Using catheter tip syringe
FDA Product Code	PIF	KNT
Sterilization	Non-sterile	Non-sterile
Silk thread	Utilized for patient comfort and proposed to be included in the kit	Utilized in clinical practice for patient comfort but not included in the kit
Detection of airway misplacement	Utilizes inflation of the tube distal end balloon at 30 cm depth mark and observing pulse oximetry and CO2 sampling	Utilizes inflation of the tube distal end balloon at 30 cm depth mark and observing pulse oximetry

5.12 Conclusions Drawn from Non-Clinical Testing

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the proposed device (K191784) is as safe, as effective, and performs as well as the identified predicate legally marketed device (K160787) and support a determination of substantial equivalence.

5.13 Conclusion

The Gabriel Feeding Tube with Balloon and ENFit connector (K191784) is substantially equivalent to our predicate device Gabriel Feeding tube with Balloon (K160787). Based on the intended use, principal of operation, performance characteristics, and technological characteristics, the proposed Gabriel Feeding Tube with Balloon and EnFit connector is substantially equivalent to and as safe, as effective, and performs as the legally marketed predicate device.