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SECTION 5. 510(K) SUMMARY

OCT 3 1 2007

Submitter:	Syncro Medical Innovations, Inc. 20 West Federal Suite M-5B Youngstown, OH 44503
Submission Correspondent:	William G. McLain President and Principal Consultant Keystone Regulatory Services, LLC. Phone: 717-656-9656 Fax: 717-656-3434 Email: bill.mclain@keystoneregualtory.com
Date summary prepared:	September 28, 2007
Device trade name:	Gabriel Blue Tube Magnetically Guided Enteral Feeding Tube
Device common name:	Feeding Tube
Device classification name:	Tube, Feeding 78 KNT at 21 CFR Part 876.5980
Legally marketed devices to which the device is substantially equivalent:	Gabriel Blue Tube Magnetically Guided Feeding Tube (Formerly named the MagnaFlow® Magnetically Guided Enteral Feeding Tube), K021991
Description of the device:	The Gabriel Blue Tube serves as a conduit through which enteral feeding solutions are directly infused into the patient's small bowel. The device will be marketed in one length (50" [127cm]) and one French size (11 Fr). The feeding tube contains a stylet which has magnets attached to its tip. An external magnet is used to capture the tip and guide the device to the duodenum. A reed switch and light indicate when the magnet has been captured and can be guided to its final location.
Intended use of the device:	The device is intended for direct placement into the small bowel. The tube functions as a conduit to facilitate enteral feeding, and may be used in pediatric, adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with a functioning gut who require short- to moderate-term feeding support, such as post-trauma patients, post-surgical patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists, or may result, secondary to an underlying disease or condition. The external steering magnet functions as a guidance tool to assist in the safe, rapid placement of the feeding tube into the small bowel.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s).

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Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: • Tensile • Flow • Flexibility • Biocompatibility
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2007

Syncro Medical Innovations, Inc.
c/o Mr. William McLain
President and Principal Consultant
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
LEOLA PA 17540

Re: K072787
Trade/Device Name: Gabriel Blue Tube Magnetically Guided Enteral Feeding Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: September 28, 2007
Received: October 1, 2007

Dear Mr. 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. 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 (PMA), 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.

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

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

Enclosure

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SECTION 6. INDICATIONS FOR USE STATEMENT

510(k) Number: K072787

Device Name: Gabriel Blue Tube Magnetically Guided Enteral Feeding Tube

Indications for Use: The Gabriel Blue Tube Magnetically Guided Enteral Feeding Tube is intended for direct placement into the small bowel. The tube functions as a conduit to facilitate enteral feeding, and may be used in pediatric, adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with a functioning gut who require short- to moderate-term feeding support, such as post-trauma patients, post-surgical patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists, or may result, secondary to an underlying disease or condition.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072787