November 5, 2020

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

Re: K201741
Trade/Device Name: Gabriel 3 Way EnFit Valve
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF
Dated: October 26, 2020
Received: October 30, 2020

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. 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.

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,

Shanil P. Haugen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K201741

Device Name

Gabriel 3-Way EnFit Valve

Indications for Use *(Describe)*

The Gabriel 3-way EnFit valve is a three-way closed system valve with three ports for control of fluid flow (nutrition, medication and water) between devices with EnFit connectors and catheter tip syringe. It can be used in pediatric, adult and elderly patients, for up to 7 days.

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.

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5. 510(k) Summary

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

5.1 Submitter Information

Company:	Sabry Gabriel MD, President Syncro Medical Innovations, Inc. 515 Mulberry Street 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 Street Macon, GA 31201-6308 USA Telephone: (478)-335-8311 Fax: (716)-809-3504 sabrygabriel@syncromedical.com
Date Summary Prepared:	October 26, 2020

5.2 Name of the Device

Trade Name:	Gabriel 3-Way EnFit Valve (K201741)
Common Name:	Stopcock, 3-way valve. Gastrointestinal Tubes With Enteral Specific Connector and Accessories
Classification Name:	Gastrointestinal tube 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 3-Way EnFit Valve (K201741) is equivalent to the LOPEZ VALVE TM II (K915171), manufactured by ICU MEDICAL, INC..

5.4 Basis for Substantial Equivalence

The device has identical intended use, indications for use, intended population, material and functionality as the predicate device "Lopez Valve" (K915171), cleared on 02/07/1992 and its' updated version with EnFit ports.

It is intended to control fluid flow (nutrition, medication and water) between EnFit compatible devices and catheter tip syringe, without frequent connection and disconnection of the associated devices.

The device passed all mechanical and biocompatibility tests listed in subsequent sections.

5.5 Legally Marketed Device to Which the proposed Device is Substantially Equivalent (Predicate Device):

ICU Medical Lopez Valve (K915171)

5.6 Device Description

The Gabriel 3-way EnFit Valve is a three-way stopcock valve that is intended to control fluid flow between enteral devices (feeding tubes and feeding lines) with EnFit compatible connectors in a closed system fashion that reduces the need for frequent connection and disconnection of the EnFit ports. It has one male EnFit port, one female EnFit port and one catheter tip port. The catheter tip port can be used for flushing and administration of medication using a catheter tip syringe. The male EnFit port is provided with a tethered cap and the catheter tip port is provided with a tethered cap. The ability to use a catheter tip syringe for flushing and administration of medicine in health care facilities that do not carry EnFit syringes, may facilitate adoption of feeding tubes and feeding lines with EnFit connectors.

5.7 Indication for use

The Gabriel 3-way EnFit valve is a three-way closed system valve with three ports for control of fluid flow (nutrition, medication and water) between devices with EnFit connectors and catheter tip syringe. It can be used in pediatric, adult and elderly patients, for up to 7 days.

5.8 Summary of Technologic Characteristics

The Gabriel 3-way EnFit valve is similar in design and technological characteristics to the predicate device cleared under K915171, ICU Medical Lopez Valve. Variations from the predicate device design are nonsignificant. The table below shows a side by side comparison of the key attributes associated with the proposed device and the predicate device.

Table 5.1: Table 1: Comparison of the proposed and Predicate Device

Attribute	Proposed Device (K201741)	Predicate Device (K915171)	Comparison Analysis
Product Name	Gabriel 3-way EnFit valve	ICU Medical Lopez Valve	**N/A**
Intended Use	Intended for use in providing access to enteral systems without opening or	Intended for use in providing access to enteral systems without opening or	**Same**

	disconnecting the fluid delivery lines.	disconnecting the fluid delivery lines.	
Indication for Use	The Gabriel 3-way EnFit valve is a three-way closed system valve with three ports for control of fluid flow (nutrition, medication and water) between devices with EnFit connectors and catheter tip syringe. It can be used in pediatric, adult and elderly patients, for up to 7 days.	Note: The predicate's device 510(k) Summary or Indications for Use Statement are not publicly available.	**N/A**
Regulation Name/ Number	21 CFR/876.5980- Gastrointestinal tube and accessories	21 CFR/876.5980- Gastrointestinal tube and accessories	**Same**
Product Code	PIF	KNT	**Different** Note: Currently the predicate device's design has been updated to include ENFit connector. Refer to its promotional material
Materials	Valve Body: Copolyester Valve Knob: High Density Polyethylene (HDPE) Valve Ports: Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS) Male EnFit Port Cap: ABS Catheter port Cap and Tether: Polyolefin Male EnFit Cap Tether: PVC	Valve Body: Polycarbonate Valve Core: Low Linear density polyethylene. Cap: Polyethylene.	**Similar**
Design Features	Three-way stopcock with: One rigid male EnFit port with tethered cap. One rigid female EnFit port. One rigid female catheter tip port with	Three way stopcock with: One rigid male catheter tip port, **one rigid female catheter tip port,** one flexible female catheter tip port and On-Off 360° rotation handle . *Note*: The updated three-way EnFit Lopez valve	**Similar**

	tethered cap. On-Off 360° rotation handle.	has: **One male EnFit port with tethered cap, o**ne male EnFit port without cap, o**ne female EnFit port and** On-Off 360° rotation handle.	
Product Configuration	Non-sterile	Sterile and non-sterile configuration	**Different**
Packaging	Individually packaged in s soft poly film pouch.	Individually packaged in soft poly film pouch.	**Same**
Performance Characteristics	The following performance characteristics are equivalent to the predicate device: • Flow rate • EnFit connectors compliant with ISO 80369-3 • Dimensional verification test of the male EnFit port, female EnFit port and catheter tip port. • Tensile test	The following performance characteristics are equivalent to the proposed device: • Flow rate • EnFit connectors compliant with ISO 80369-3	**Same**
Prescription vs. OTC	Prescription only	Prescription only	**Same**
Duration of Use	Less than 7 days Change valve per institutional protocol and as needed.	Acute care: less than 7 days Other care settings: May be used longer.	**Same**
Single Use vs. Reusable	Single use	Single use	**Same**
Shelf Life	One year	Not stated	N/A

5.9 Summary of Testing (Bench)

Non-clinical verification of the Gabriel 3-way EnFit valve has been conducted on devices that were manufactured 12 months earlier to evaluate its' safety, performance and functionality. The results of these tests have demonstrated the overall safety of the proposed device and ultimately support a substantial equivalence determination to the predicate , ICU Medical Lopez Valve (K915171). A summary of testing is presented below.

Male EnFit Measurement Verification Test (PASS)

Female EnFit Measurements Verification Test (PASS)

Catheter Tip Port Measurement Verification Test (PASS)

Tensile Test (PASS)

Cytotoxicity test (PASS)

Sensitization Test (PASS)

Irritation Test(PASS)

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)

Flexure modulus above 700 Mpa (PASS)

Feeding Formula Flow Rate Test (PASS)

5.10 Biocompatibility Testing

The following biocompatibility tests were conducted on the entire Gabriel 3-way EnFit valve per ISO 10993-1:

- Cytotoxicity test (PASS).

- Sensitization test(PASS)

- Irritation test (PASS).

The biocompatibility test results indicates that the Gabriel 3-way EnFit Valve is considered to be non-cytotoxic, non-sensitizing, and non-irritant. Collectively, the test results indicate that the product meets the biocompatibility requirements and is considered safe for its intended use.

5.11 Conclusions Drawn from Non-Clinical Testing

The results of comparison of design, material, intended use, technological characteristics and bench tests demonstrate that the proposed device is as safe, as effective, and performs as the identified predicated legally marketed device (K915171) and supports a determination of substantial equivalence.

5.12 Performance Testing (Animal)

This section does not apply. No animal testing was performed.

5.13 Performance Testing (Clinical)

This section does not apply. No animal testing was performed.

5.14 Conclusion

The Gabriel 3-way EnFit Valve is substantially equivalent to the predicate ICU Medical Lopez Valve (K915171). Based on the indication for use, principal of operation, performance characteristics, and technological characteristics, the proposed Gabriel 3-way EnFit valve is substantially equivalent to, and as safe, as effective, and performs as the legally marketed predicate device.