April 20, 2022

Synovis Micro Companies Alliance, Inc.
Julie Carlston
Senior Manager, Regulatory Affairs
(a Subsidiary of Baxter International Inc.)
439 Industrial Lane
Birmingham, Alabama 35211

Re: K213974
Trade/Device Name: GEM FLOW COUPLER Monitor (GEM1020M-2)
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW, MVR
Dated: March 11, 2022
Received: March 14, 2022

Dear Julie Carlston:

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,

for Deborah Fellhauer, RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K213974

Device Name
GEM FLOW COUPLER Monitor (GEM1020M-2)

Indications for Use *(Describe)*
The FLOW COUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FLOW COUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the FLOW COUPLER Device is used in conjunction with the FLOW COUPLER Monitor, the FLOW COUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site. Post-operatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW COUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.

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.

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510(k) Summary

I. Submitter

Synovis Micro Companies Alliance, Inc.
(A Subsidiary of Baxter International, Inc.)
439 Industrial Lane
Birmingham, AL 35211-4464
Establishment Registration Number: 1062741

Julie Carlston
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Date Prepared: April 14, 2022

II. Subject Device

Device Trade Name	GEM FLOW COUPLER Monitor (GEM1020M-2)
Common Name	Cardiovascular Blood Flowmeter
Classification Name	Flowmeter, Blood, Cardiovascular Regulation Number: 21 CFR 870.2100 Classification: Class II Implantable Clip Regulation Number: 21 CFR 878.4300 Classification: Class II
Product Code	MVR, DPW

III. Predicate Device

Device Trade Name	GEM FLOW COUPLER System; K191252
Common Name	Cardiovascular Blood Flowmeter
Classification Name	Flowmeter, Blood, Cardiovascular Regulation Number: 21 CFR 870.2100 Classification: Class II Implantable Clip Regulation Number: 21 CFR 878.4300 Classification: Class II
Product Code	MVR, DPW

IV. Device Description

The GEM FLOW COUPLER System is designed for the detection of blood flow in vessels. The GEM FLOW COUPLER System consists of components as described below:

1. FLOW COUPLER Device (Product Code MVR) - single-use implantable rings used to secure anastomosis of small vessels. This includes a 20MHz ultrasonic Doppler transducer (probe) which attaches to one of the FLOW COUPLER rings, and an external lead.

2. FLOW COUPLER Monitor (Product Code DPW) - portable monitor that provides the audible output of the FLOW COUPLER Device's pulsed Doppler ultrasound signal. A varying audible signal is produced when the FLOW COUPLER Device (probe) detects flow.

The predicate device (K191252) submission included an additional optional remote monitoring capability for the remote retrieval of FLOW COUPLER Monitor data via the GEMflow App (which is part of the GEM Cloud System). This optional remote monitoring capability was not extensively utilized and has been excluded from the subject device. The remote monitoring capability is not available with the subject devic.

V. Intended Use / Indications for Use

The Intended Use and Indications for Use remain the same as the predicate device (K191252).

Intended Use

The FLOW COUPLER Device and System is intended to be used in the anastomosis of veins and arteries normally encountered in microvascular and vascular reconstructive procedures and in the detection of blood flow and confirmation of vessel patency following end-to-end anastomosis of vessels.

Indications for Use

The FLOW COUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FLOW COUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the FLOW COUPLER Device is used in conjunction with the FLOW COUPLER Monitor, the FLOW COUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site. Post-operatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW COUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.

VI. Comparison of Technological Characteristics with the Predicate Device

The overall functionality and features necessary to support the device's intended use remain unchanged from the previous device clearance (K191252). Minor modifications to the product hardware, firmware and labeling have been made in this submission:

- Power management update (monitor firmware update): revised logic for handling a battery-protection shutdown scenario.

- Power button update (monitor hardware update): recessed the button to be flush with the device bezel and increased the contact force.
- Audio system update (monitor hardware update): updated speaker assembly and capacitors on Printed Circuit Board Assembly to reduce background noise and enhance overall audio clarity.
- List of approved cleaning solutions update (labeling update): updated Instructions for Use with an expanded list of approved cleaning solutions.
- Disabling of the optional remote monitoring capability: updated monitor firmware to disable the connection to the cloud backend server (GEM Cloud System) to disable the optional remote monitoring capability.

The technological characteristics and specifications of the FLOW COUPLER Monitor have been evaluated against its predicate device (previous version of the subject device) to determine equivalence.. A summary of the comparison between the predicate and subject devices is provided in Table 1 below.

Table 1 - FLOW COUPLER Monitor Predicate and Subject Devices - Comparison Table

Attribute	Predicate Device	Subject Device
Product Name	GEM FLOW COUPLER System	Same
510(k)-holder	Synovis Micro Companies Alliance, Inc. (A Subsidiary of Baxter International, Inc.)	Same
510(k) Number	K191252	K213974
Product Code	MVR, DPW	Same
Regulation	21 CFR 878.4300 21 CFR 870.2100	Same
Classification	Class II	Same
Intended Use	The FLOW COUPLER Device and System is intended to be used in the anastomosis of veins and arteries normally encountered in microvascular and vascular reconstructive procedures and in the detection of blood flow and confirmation of vessel patency following end-to-end anastomosis of vessels.	Same
Indications for Use	The FLOW COUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FLOW COUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the FLOW COUPLER Device is used in conjunction with the FLOW COUPLER Monitor, the FLOW COUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site. Post-operatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW COUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.	Same
Product Use Environment	Hospital Operating Room and Post-Anesthesia Care Unit	Same
End Users of Product	Nurses and surgeons	Same
Dimensions	6.17” D x 8.18” W x 3.20” H	Same
Weight	1.8 lb. (0.8 kg)	Same

Acoustical Output	Acoustical Power will be less than 94 mW/cm2	Same
Depth	Not selectable	Same
Transmission Frequency	20 MHz	Same
Transmission Characteristic	Pulsed wave transmission, continuous reception	Same
Pulse Repetition Frequency	156.25 KHz	Same
Energy Used and/or Delivered	12 Volts direct current supplied by A/C to D/C converter Rechargeable internal lithium ion battery pack	Same
Power Input	Input Voltage: 90-264 VAC Frequency: 47-63 Hz	Same
Power Output	Total Output Power: 30 watts Voltage: 12VDC Current: 2.5A Output Regulation ± 5%	Same
Power management update		
Monitor firmware	Analog Front End, Doppler phase shift detection, plus FFT filtering, noise reduction, and background noise reduction	Revised logic for handling a proper battery-protection shutdown scenario to prevent complete battery drainage and inoperable monitor
Power button update		
Power button	Location: rear of unit Elevation: raised (3.50 mm)	Location: rear of unit Elevation: flush with device bezel Activation force: 400gf
Audio system update		
Printed Circuit Board Assembly (PCBA)	PCBA per K191252	PCBA components have been changed to improve audio quality
Speaker Assembly	57.5mm wide, 3W Max. Power speaker Concave speaker grill	60mm wide, 4W Max. Power speaker Convex speaker grill
List of approved cleaning solutions update		
Cleaning instructions	Wipe the Monitor with a dry or water-moistened soft cloth. Ensure any residual organic material is removed. Do not pour or spray liquid directly on the Monitor. Allow to air dry before use.	Wipe the Monitor with a dry or water-moistened soft cloth, Isopropyl Alcohol, Ammonium Hydroxide based surface cleanser, Ammonium Chloride based surface cleanser or 2% bleach solution. Ensure any residual organic material is removed. Do not pour or spray liquid directly on the Monitor. Allow to air dry before use.
Disabling of the optional remote monitoring capability		
Remote Access Function (Optional)	Android and iOS App to access audio files remotely	Disabled optional remote monitoring capability

VII. Performance Data

Synovis conducted performance testing to evaluate safety and effectiveness of the FLOW COUPLER Monitor to support substantial equivalence to the predicate device, as well as to evaluate that product requirements are met. The following testing of the FLOW COUPLER Monitor has been performed.

Performance Testing	Acceptance Criteria	Result
FLOW COUPLER Monitor cleaning per IEC 60601-1:2005+AMD1:2012 section 11.6.6 FLOW COUPLER Monitor Cleaning Conditioning	• Passing inspection for the damage and post-test leakage and dielectric test. • Functioning monitor after the cleaning.	Pass
FLOW COUPLER Monitor Design Inspection and Functional Demonstration	• The power switch meets design and functional specifications	Pass
FLOW COUPLER Monitor Audio Quality Testing	• Audio level greater than 70dB • Signal to Noise ratio of the output electrical signal to the speaker shall be greater than 20 at all tested frequencies • Total Harmonic Distortion (THD) within specification at varying frequencies	Pass
FLOW COUPLER Monitor EMC Testing	• IEC 60601-1-2 Edition 4.1: 2020 Class A for Emissions, Immunity for Professional Healthcare Facility Environment And 47 CFR, Part 15:2022, §15.107 and §15.109, Class A	Pass

Applicable verification and validation testing was completed with passing results per the predefined acceptance criteria for each test case. These results support that the modified device performs as intended, and meets all functional requirements and performance specifications.

VIII. Conclusions

The FLOW COUPLER System indications for use and principles of operation remain unchanged (are the same as the predicate device). Performance testing has been completed to evaluate safety and effectiveness of the subject device as it compares to its predicate. The conclusion drawn from the risk-benefit assessment and nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device. No new issues of safety and effectiveness have been identified.