July 9, 2019

Baxter/Synovis Micro Companies Alliance, Inc.
% Ms. Julie Carlston
Senior Regulatory Affairs Manager
Synovis Micro Companies Alliance, Inc.
2875 University Avenue West
St. Paul, Minnesota 55114

Re: K191252
Trade/Device Name: GEM™FLOW COUPLER™ Monitor (GEM2010M-2)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: MVR, DPW
Dated: May 8, 2019
Received: May 9, 2019

Dear Ms. 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,

Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191252

Device Name
Flow Coupler Device

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.

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."

510(K) Summary

I. Submitter

Synovis Micro Companies Alliance, Inc.
A Subsidiary of Synovis Life Technologies, Inc. 439 Industrial Lane
Birmingham, AL 35211-4464

Julie Carlston
Synovis Micro Companies Alliance, Inc.
A Subsidiary of Synovis Life Technologies, Inc. 2575
University Avenue West
St. Paul, MN 55114-1024 Tel: 651-796-7511
Fax: 651-642-9018
julie_carlston@baxter.com

Date of preparation: May 8, 2019

II. Device

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

III. Predicate Device

Predicate Device	GEM FLOW COUPLER Device and System; K093310 (includes GEM FLOW COUPLER Monitor - GEM1020M)

IV. Device Description

The FLOW COUPLER Device and System consists of a FLOW COUPLER Device and a FLOW COUPLER Monitor. The FLOW COUPLER Monitor is a pulsed Doppler ultrasound system designed for the detection of blood flow in vessels. The FLOW COUPLER Device includes a 20MHz ultrasonic Doppler transducer (probe) attached to one of the FLOW COUPLER rings, and an external lead. The probe via the external lead connects to the monitor and emits a pulsed ultrasonic signal. A varying audible

signal is produced when the probe detects flow.

V. Indication for Use

The indications for use of the FLOWCOUPLER device are the same as those cleared previously in K093310:

> 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.

VI. Comparison of Technological Characteristics with the Predicate Device

The most notable technological differences between the predicate and proposed device are that the modified monitor includes a color LCD touchscreen as the user interface, adds a qualitative visual display as a secondary indicator of blood flow, and has wireless capability for remote access to previously recorded audio. While both monitors have the same analog front end for generating the electrical signal to the probe, the modified monitor also includes software for digital filtering of the returned audio signal for noise reduction. In addition, an internal rechargeable lithium battery pack replaces AA (LR6) batteries as the alternate power source.

Bench testing of the modified device showed that these technological differences do not impact the safety and essential performance of the monitor. The performance data described in this submission confirm that the modified monitor meets the same performance specifications as the predicate device.

VII. Performance Data

Testing of the FLOW COUPLER Monitor includes the following:

- EMC Testing

- Electrical Safety Testing
- Acoustic Output Testing
- AC Power Continuous Use
- Battery Life Testing
- User Interface Functional Testing
- Flow Velocity Testing
- Functional Performance Testing
- Packaging Validation Testing
- Software Verification

The results of testing have been provided for the modified monitor. The testing was completed with passing results per the pass/fail criteria defined for each test case. These results support that the modified monitor is substantially equivalent to the predicate device.

The intended use of the modified FLOW COUPLER Monitor is identical to the predicate device. This submission includes information on the technological characteristics of the modified monitor, as well as performance data demonstrating that the proposed monitor is as safe and effective as the predicate device, and does not raise different questions of safety and effectiveness for its intended use.

VIII. Conclusions

The FLOW COUPLER device and system has the same indications for use and principles of operation as the predicate device. The modified monitor has the same indications for use as the predicate device, meets the same performance specifications, and applies the same fundamental scientific technology for audio observation of the anastomosis. Testing supports that the device is as safe and effective for its intended use as the predicate device. Synovis MCA concludes that the modified FLOW COUPLER Monitor is substantially equivalent to the predicate device