January 28, 2024

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

Re: K233394
Trade/Device Name: GEM FLOW NOW (GEM2770-FN)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX
Dated: October 3, 2023
Received: October 3, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K233394

Device Name
GEM FLOW NOW (GEM2770-FN)

Indications for Use *(Describe)*
FLOW NOW is indicated for monitoring blood flow in peripheral vessels during and following reconstructive microvascular procedures, re-implantation, and free flap transfers. Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW NOW Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.

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.

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510(k) Summary

I. Submitter's Information

Company Name: Synovis Micro Companies Alliance (A subsidiary of Baxter International Inc.)
Address: 439 Industrial Lane, Birmingham Alabama, 35211, USA
Establishment Registration Number: 1062741

Contact Person: Julie Carlston
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Email Address: julie_carlston@baxter.com

Date Prepared: October 3, 2023

II. Device Information

Trade Name: GEM FLOW NOW (GEM2770-FN)
Common Name: Ultrasonic pulsed doppler imaging system
Classification Name: System, Imaging, pulsed Doppler, Ultrasonic
Regulatory Class: Class 2
Regulation: 892.1550
Product Code: IYN, ITX

III. Predicate Device

GEM Flow Coupler Device and System K143589 (Reference device: Cook-Swartz Doppler Probe K171272)

IV. Device Description

The GEM FLOW NOW (FLOW NOW) device is comprised of an implantable non-active silicone vessel sleeve (Figure 2), a 20 MHz ultrasonic Doppler transducer (probe) and probe wire, suture sleeve, probe connector, and an external lead that connects to a monitor. FLOW NOW has a soft, pliable silicone "vessel sleeve" that retains the Doppler probe via press-fit into a silicone bore. The device comes with vessel sleeve and probe already assembled.

The FLOW NOW Device is intended for monitoring blood flow in vessels. It is indicated for monitoring blood flow in peripheral vessels intraoperatively, and following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers. Post-operatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW NOW Doppler probe

is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively. The FLOW NOW device is intended for use with both currently cleared FLOW COUPLER Monitors (GEM1020M and GEM1020M-2).

The probe is removed from the patient 3 to 14 days after implantation, once monitoring is complete. The probe is separated from the vessel sleeve and removed from the patient's body, non-invasively, by the surgeon pulling on the probe wire outside the patient's body. The silicone vessel sleeve remains permanently implanted. The FLOW NOW device can be used to monitor blood flow through veins and arteries ranging from 2.0 to 4.0 mm in outside diameter.

V. Indications for Use

FLOW NOW is indicated for monitoring blood flow in peripheral vessels during and following reconstructive microvascular procedures, re-implantation, and free flap transfers. Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW NOW Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.

VI. Intended Use

FLOW NOW is intended for monitoring blood flow in vessels.

VII. Technological Characteristics

The technological specification of the GEM FLOW NOW and its predicate device have been evaluated to determine equivalence. As detailed in the Substantial Equivalence section of this 510(k) submission, upon reviewing and comparing intended use, design, principle of operation and overall technology characteristics, GEM FLOW NOW is determined by Synovis Micro Companies Alliance to be substantially equivalent to existing legally marketed devices (Table 1).

Table 1: Overview of Substantial Equivalence

	Subject Device	Predicate Device	Determination
Product Name	GEM FLOW NOW	GEM FLOW COUPLER System	NA
510(k) Holder	Synovis Micro Companies Alliance, Inc, a subsidiary Of Baxter International Inc.	Synovis Micro Companies Alliance, Inc, a subsidiary Of Baxter International Inc.	NA
510(k) Number	TBD	K143589	NA
Product Code	IYN, ITX	MVR, DPW	Equivalent
Regulation	892.1550	878.4300	Equivalent
Classification	Class II	Class II	Same

	Subject Device	Predicate Device	Determination
Intended Use	FLOW NOW is intended for monitoring blood flow in vessels.	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.	Equivalent
Indications for Use	FLOW NOW is indicated for monitoring blood flow in peripheral vessels during and following reconstructive microvascular procedures, re-implantation, and free flap transfers. Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW NOW Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.	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 intraoperatively 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.	Equivalent.
How Supplied	Sterile, single use	Sterile, single use	Same
Principle of operation	Silicone vessel sleeve is secured around the target vessel with a vascular clip, with the probe in liquid contact with the vessel wall.	FLOW COUPLER Device implantable rings are used to perform end-to-end anastomosis of blood vessels. The removable doppler probe is provided	Equivalent

	Subject Device	Predicate Device	Determination
	The Doppler probe is connected to the FLOW COUPLER Monitor via the external lead, which allows it to transmit a Doppler signal caused by blood flow. The probe wire is secured at the skin entry site using the suture sleeve. Once function is confirmed, the surgical site is closed using standard techniques, with the vessel sleeve and Doppler probe implanted. The Doppler probe remains in place for 3-14 days, at which point it is removed. The silicone vessel sleeve is permanently implanted.	attached onto one of the rings and the probe lead is connected to the FLOW COUPLER Monitor, which detects blood flow. Once function is confirmed, the surgical site is closed using standard techniques, while the rings and Doppler probe remain in place, and the probe lead is secured at the skin entry site. The doppler probe remains in place for 3-14 days, at which point it is removed. The rings permanently implanted.	
Compatible Monitor	GEM FLOW COUPLER Monitor	GEM FLOW COUPLER Monitor	Same
Time from implantation to probe removal	3-14 days	3-14 days	Same
Monitoring Duration	7 days	7 days	Same
Vessel size	2-4mm OD	2-4 mm OD	Same
Biocompatibility	Per ISO 10993	Per ISO 10993	Same
Sterilization	10^{-6} SAL (EtO)	10^{-6} SAL (EtO)	Same

VIII. Performance Data

Non-Clinical

Bench performance testing was performed after applicable aging, distribution, environmental and/or implantation conditioning to evaluate and compare the technological and performance characteristics. Pre-determined performance specifications were tested, and verification and validation activities were conducted to demonstrate that the GEM FLOW NOW met the defined criteria.

Performance evaluation of the GEM FLOW NOW during the design validation and verification was completed by applying methods of internationally recognized standards such as, EN ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process, EN ISO 11737-2:2009, Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process, EN IEC 62366: 2015, Medical devices – Application of usability engineering to medical device, among others.

The GEM FLOW NOW met acceptance criteria and demonstrated comparable performance to the predicate device for the equivalent indications for use.

Clinical

Clinical performance testing was not required for the GEM FLOW NOW device.

IX. Conclusion

The device is substantially equivalent to the predicate device with respect to indications for use, and technological characteristics and does not raise new questions of safety and effectiveness.