September 6, 2019

Baxter/ Synovis Micro Companies Alliance Inc.
Julie Carlston
Sr. Dept. Specialist/ R & D
2875 University Ave. West
St. Paul, Minnesota 55114

Re: K190499
Trade/Device Name: GEM FlowCoupler System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: MVR, DPW
Dated: August 1, 2019
Received: August 9, 2019

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,

Cindy Chowdhury, Ph.D., M.B.A
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190499

Device Name
GEM FlowCoupler System

Indications for Use *(Describe)*
The VESSEL EVERTER System is indicated for use with the Microvascular Anastomotic COUPLER and FLOW COUPLER Device in the anastomosis of only arteries normally encountered in microsurgical procedures only in the peripheral vascular system. The VESSEL EVERTER System is indicated for use with COUPLER and FLOW COUPLER System sizes from 2.0 to 4.0 mm.

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. Name of Submitter, Contact Person, and Date Prepared:**


| | |
|---|---|
| Name: | Baxter/ Synovis Micro Companies Alliance Inc. |
| Address: | 2875 University Ave. West<br>St. Paul, MN 55114 |
| Telephone: | 651-796-7511 |
| Contact Person | Julie Carlston |
| Telephone: | 571-299-9806 Mobile |
| Email: | julie_carlston@baxter.com |
| Date Prepared: | August 1, 2019 |


**II.** DEVICE

a. 510(k) Number: K190499
b. Trade Name: GEM FlowCoupler System
c. Common Name: Implantable clip and accessories
d. Classification Name: Device, Anastomotic, Microvascular
e. Classification Regulation: 21 CFR 878.4300
f. Device Classification: Class II
g. Classification Product Code: MVR and DPW
h. Panel: General and Plastic Surgery

**III.** PREDICATE DEVICE:

K143589 GEM FlowCoupler System
This predicate has not been subject to a design-related recall.

PERFORMANCE STANDARDS

None required under Section 514 of the Act

**IV.** DEVICE DESCRIPTION

Two accessory devices comprise the Vessel Everter System: Vessel Everter and Sizing Guide. The Vessel Everter system is an accessory device to the GEM FLOWCOUPLER System, a pair of implantable rings that are used for end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures.

The Vessel Everter System are two non-implantable, sterile, single use hand-held devices that facilitate sizing and use of the GEM FLOWCOUPLER System. The Vessel Everter is comprised of a handle with two soft silicone end effectors (tips), one on each end. The instrument handle features two separate silicone end effectors, each of a different size, intended to be used at the surgeon's discretion. The Vessel Everter end effector is designed with a narrowing tip to allow for engagement with multiple sizes of vessels, corresponding with a coupler size of 2.0-4.0 mm rings. The Vessel Everter is used to press vessel tissue onto the GEM FLOWCOUPLER rings. To accomplish this, the surgeon presses the Vessel Everter into the tissue, flaring the tissue onto and over the Coupler locking pins.

The Sizing Guide is a hard, plastic handle featuring holes on either end through which the vessel's outer diameter may be measured. The holes' diameters are intended to match the

inner diameters of the various GEM FLOWCOUPLER rings. The holes correlate to vessel diameters of 2.0 mm to 4.0 mm in 0.5 mm increments. The surgeon may use the sizing guide to guide the selection of which coupler they will use for each particular anastomosis. The Sizing Guide is used by placing the vessel on the sizing guide and comparing the vessel diameter to the holes in the Sizing Guide.

The Vessel Everter and Sizing Guide are sterilized by ethylene oxide and are provided sterile for-single-patient use. The Vessel Everter and Sizing Guide are not implantable and are disposed of after single use.

The parent device, GEM FLOWCOUPLER System, remains unchanged and is not addressed in this submission.

## V. INDICATIONS FOR USE

The accessory device Indications for Use are as follows:

> The VESSEL EVERTER System is indicated for use with the Microvascular Anastomotic COUPLER and FLOW COUPLER Device in the anastomosis of only arteries normally encountered in microsurgical procedures only in the peripheral vascular system. The VESSEL EVERTER System is indicated for use with COUPLER and FLOW COUPLER System sizes from 2.0 to 4.0 mm.

The indications for use for the parent device (GEM FLOWCOUPLER System) remain unchanged:

> The FlowCOUPLER Device is a single use, implantable device that is intendedto be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FlowCOUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-f it onto one of the rings. When the FlowCOUPLER Device is used in conjunction with the FlowCOUPLER Monitor, the FlowCOUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomnotic site. Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The FlowCOUPLER 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

Comparison to Predicate Device: This premarket notification describes addition of two accessories for single-patient-use: a disposable single use Vessel Everter and Sizing Guide. The system currently includes reusable Vessel Everter and Sizing Guide accessory devices (the predicate devices) which the disposable accessories will replace.

The subject Vessel Everter device has the same intended use as the predicate, reusable Vessel Everter accessory; both assist the surgeon in placing the vessel over the Coupler.

The subject single-patient-use Sizing Guide has the same intended use as the predicate reusable Sizing Guide to assist the surgeon in determining appropriate coupler size. The subject and predicate devices differ in materials (plastic vs. metal) and the subject device is provided sterile unlike the predicate which requires the user to sterilize prior to use. The subject and predicate accessories are equivalent with regard to intended use, target population, anatomical site, use setting, performance, compatibility with the environment and other devices, and biocompatibility. The subject device accessories differ from the predicate device accessories primarily with respect to sterile state (sterilization method) and materials.

## VII. PERFORMANCE TESTING

| Test | Test Method Summary | Results |
|---|---|---|
| Silicone tip retention tensile force verification testing | Measurement of tension force required to completely dissociate the silicon tip from the barbed handle. | Subject devices met acceptance criteria |
| Retention Barb Cantilever Loading Verification Testing | Measurement of force required to dissociate the silicon tip from the barbed handle tested by applying a compressive load perpendicular (90°) to the axis of the retention barb | Subject devices met acceptance criteria |
| Coupler Engagement and Disengagement Force Verification | Measurement of force required to disengage everter vessel silicone tip from coupler pins, force to pierce the coupler pins, and number of penetrations onto the coupler barbs | Subject devices met acceptance criteria |
| Intimal Integrity Verification Testing | Use of the device in porcine vessels. Evaluation of force that anastomosis can withstand without a full-thickness dissection of the intima in porcine vessels | Subject devices met acceptance criteria |

## VIII. BIOCOMPATIBILITY TESTING

| **Test Name** | **Result** | **Disposition** |
|---|---|---|
| Cytotoxicity - L929 MEM Elution | Not cytotoxic per ISO10993-5 | PASS |
| Sensitization – Kligman Maximization test | Non-sensitizer per ISO10993-10 | PASS |

| Test Name | Result | Disposition |
|---|---|---|
| Irritation – intracutaneous injection in rabbit | Negative per ISO10993-10 | PASS |
| Toxicity – systemic injection in mouse | Negative for toxicity per ISO10993-11 | PASS |
| Rabbit blood hemolysis test | Non-hemolytic per ASTM F756 | PASS |

## IX. CLINICAL STUDIES

Clinical studies were not required to support substantial equivalence between the reusable accessories and the single-patient-use accessories.

## X. SUBSTANTIAL EQUIVALENCE

The subject device accessories have the same intended use as the predicate accessories and the same technological characteristics. Testing in porcine vessels demonstrates that the device may be used per its intended use. There are no new types of questions of safety and effectiveness and the Vessel Everter and Sizing Guide are substantially equivalent to the predicate accessories.