September 14, 2022

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

Re: K221843
Trade/Device Name: GEM™ Biover Microvascular Clamps
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: August 12, 2022
Received: August 15, 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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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)*
K221843

Device Name
GEM™ BIOVER Microvascular Clamps

Indications for Use *(Describe)*
GEM™ BIOVER disposable microvascular clamps are instruments which are used for all microsurgical procedures. They are used to occlude vessels during anastomosis, which is necessary as a result of vessel damage or thrombosis.

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 K221843

I. Submitter

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A Subsidiary of Baxter International Inc.
439 Industrial Lane
Birmingham, AL 35211-4464
Establishment Registration Number: 1062741

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Date Prepared: September 13, 2022

II. Subject Device K221843

Device Trade Name	GEM™ Biover Microvascular Clamps
Common Name	Microvascular Clamps
Classification Name	Clamp, Vascular Regulation Number: 21 CFR 870.4450 Classification: Class II
Product Code	DXC

III. Predicate Device K011208

Device Trade Name	Biover Microvascular Clamps
Common Name	Microvascular Clamps
Classification Name	Clamp, Vascular Regulation Number: 21 CFR 870.4450 Classification: Class II
Product Code	DXC

IV. Device Description

The GEM™ Biover Microvascular Clamps (Clamps) are arterial and venous clamps in both single and double clamp configurations, available in varying sizes. The clamps are sterile, disposable clamps for single use. The clamps are used in microsurgery, plastic surgery, and hand surgery for the temporary occlusion of blood vessels during an anastomosis.

The clamps are available for arteries and veins. The clamping force is higher for the arterial clamps than for the veinous clamps. The clamps are identified by a product reference code and by the color of the clamp. The clamps for veins are green, and the clamps for arteries are yellow.

The clamps are packaged individually in two Tyvek pouches (double pouched). The devices in the Tyvek pouches are gamma sterilized and are placed in cartons of 10. The clamps are used once and are disposed of after use.

V. Intended Use and Indications for Use

The Intended Use remains the same as the predicate device (K011208).

Indication for Use
GEM BIOVER disposable microvascular clamps are instruments which are used for all microsurgical procedures. They are used to occlude vessels during anastomosis, which is necessary as a result of vessel damage or thrombosis.

The wording of the Indication for Use was modified slightly from the predicate to improve the clarity of the statement while maintaining the same intended use and scope. The indications for use statements are the same in intended clinical use and therefore there is no substantial change to the indication for use of the microvascular clamps. The similarity in the indication for use statements supports substantial equivalence.

VI. Comparison of Technological Characteristics with the Predicate Device

The device and primary packaging of the double pouch configuration (sterile packaging) remain unchanged and are identical to the predicate device. There are no engineering or performance changes to the device or its packaging. The only technology change is a minor modification to the sales unit carton (box of 10 individual pouches) which was made to ease removal of the packaged (pouched) clamps. There is no change in sterilization.

In addition to the minor change to the carton, updates were made to the Instruction Manual and package labeling to reflect the new tradename of the device.

Table 1: Predicate and subject device comparison

Attribute	**Subject of this submission** GEM BIOVER Microvascular Clamps	**Predicate Device** BIOVER Microvascular Clamps	**Comparison**
510(k) #	K221843	K011208	-
Manufacturer (Specification Developer)	SYNOVIS MICRO COMPANIES ALLIANCE, INC. (A Subsidiary Of Baxter International Inc.) 439 Industrial Ln BIRMINGHAM, AL 35211	Biover AG Muliweg 2 Hergiswil Nidwalden, CH 114-002	Change due to acquisition of Biover AG
Contract Manufacturer	DIADEM CORPORATION 582-7, Ubaga-Cho Hitachiomiya-Shi Ibaraki, JP 319-2251	DIADEM CORPORATION 582-7, Ubaga-Cho Hitachiomiya-Shi Ibaraki, JP 319-2251	Same

Attribute	Subject of this submission GEM BIOVER Microvascular Clamps	Predicate Device BIOVER Microvascular Clamps	Comparison
Intended Use	GEM BIOVER disposable microvascular clamps are used in microsurgical procedures to occlude blood vessels during anastomosis.	BIOVER disposable microvascular clamps are used in microsurgical procedures to occlude blood vessels during anastomosis.	Same
Indications for Use	Disposable microvascular clamps are instruments which are used for all microsurgical procedures. They are used to occlude vessels during anastomosis, which is necessary as a result of vessel damage or thrombosis.	BIOVER disposable microvascular clamps are used for end to end anastomotic procedures for arteries and veins. The single version is placed to stop blood flow for a certain time (less than 16 hours). The double version is used for the repair of ruptured arteries and veins.	Equivalent. Update of tradename. The differences in wording are clarifying the intended use of the device and do not constitute a change in their clinical use
General Description			
Product Use Environment	Hospital	Hospital	Same
End Users of Product	Surgeons, scrubbed persons, and nurses	Surgeons, scrubbed persons, and nurses	Same
Clamp Design	2 Types of Clamps are available 1) Clamps for arteries are yellow (single (1) and double (2)) 2) Clamps for veins are green (single (1) and double (2))	2 Types of Clamps are available 1) Clamps for arteries are yellow (single (1) and double (2)) Clamps for veins are green (single (1) and double (2))	Same
Vessel Diameter	Artery Clamps (yellow): < 1 mm, 1 mm - 2 mm, 2mm - 4mm Vein Clamps (green): 0.2 – 1 mm < 1 mm, 1 mm-2 mm, 2 mm	Artery Clamps (yellow): < 1 mm, 1 mm - 2 mm, 2mm - 4mm Vein Clamps (green): 0.2 – 1 mm < 1 mm, 1 mm-2 mm, 2 mm	Same
Contraindications	None known.	None known	Same
Labeling			

Attribute	Subject of this submission GEM BIOVER Microvascular Clamps	Predicate Device BIOVER Microvascular Clamps	Comparison
Labels and Instruction Manual for Monitor and Power Supply	See section 13 - Proposed Labeling	See section 13 - Proposed Labeling	Equivalent. Labeling was modified to reflect the new legal manufacturer. Branding updated to reflect new tradename. Indication for Use statement updated to reflect the clarified indication for use statement
Packaging	Each clamp is packaged in a double Tyvek pouch configuration. 10 pouches packed in an outer carton.	Each clamp is packaged in a double Tyvek pouch configuration. 10 pouches packed in an outer carton.	Same. Minor change to the opening geometry of the outer carton of the sales unit has no impact on the device.

VII. Performance Data

The label design change and the outer carton sales unit design change were assessed and validated in a Packaging Summative Human Factors/Usability Study. Historical complaint data were reviewed and indicate no use-related concerns, thus, there are no use-related risks or complaints that trigger a need for further Human Factors validation.

VIII. Conclusions

The GEM Biover microvascular clamps remain unchanged from the predicate device. Performance testing has been completed to evaluate safety and effectiveness of the subject device as it compares to its predicate. The conclusions 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. The proposed device is substantially equivalent to the predicate device.