March 4, 2021

Biorep Technologies, Inc.
Victoria Enjamio
Regulatory Affairs & Quality Director
15804 NW 57th Avenue
Miami Lakes, Florida 33014

Re: K210006
Trade/Device Name: MI DeTACH®
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 31, 2020
Received: January 4, 2021

Dear Victoria Enjamio:

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)*
K210006

Device Name
MI DeTACH®

Indications for Use *(Describe)*
The MI DeTACH® is indicated for use for temporary or partial occlusion of blood vessels during cardiovascular surgical procedures.

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

Name:	Biorep Technologies, Inc.
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Establishment Registration Number	3005593675
Contact Person:	Victoria Enjamio
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Secondary Contact:	Felipe Echeverri
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Date Prepared:	December 31, 2020

II. DEVICE

Proprietary Name:	MI DeTACH®
Common Name:	Vascular Clamp
Classification Name:	Clamp, Vascular
Regulation Number:	870.4450
Product Code:	DXC
Device Class:	Class II

III. PREDICATE DEVICE INFORMATION

MI DeTACH® is substantially equivalent in function and intended use to Flexline Clamp (now known as Cygnet® Flexible Clamp) (K010727) and the Cardio Vision® MICS Aortic Clamps (K123571).

IV. INDICATIONS FOR USE

The MI DeTACH® is indicated for use for temporary or partial occlusion of blood vessels during cardiovascular surgical procedures.

V. DEVICE DESCRIPTION

The MI DeTACH® is comprised of a Detachable Aortic Clamp Head and a Delivery System. The MI DeTACH® Detachable Aortic Cross Clamp Head (Figure 10.6-1) is available in three sizes: Small, Medium, and Large (55mm, 65mm, and 85mm engagement pads respectively) which are packaged and distributed separately. The Delivery System is comprised of a Delivery Device (Figure 10.6-2) and Quick Release Device (Figure 10.6-3). The Delivery Device is used to deliver, clamp, deploy, unclamp, and retrieve the Clamp Head from the target occlusion site.

The MI DeTACH® Detachable Aortic Cross Clamp Head works by applying compression forces to the vessel by the padded device jaws. The top jaw is a pivot jaw allowing for parallel closure of the vessel during clamping. The amount of compression applied to the vessel for occlusion or partial occlusion is determined or adjusted by the means of the Delivery Device lever actuated jaw closure mechanism. The Clamp Head device contains ratchets that provide clamping tactile feedback to the user. A clutch mechanism prevents the user from applying excessive forces to the vessel by disengaging the lever from the device when specific force is obtained. Upon successfully clamping, the device locks and the handle is then detached leaving the clamp in the body throughout the duration of the procedure. The Delivery Device is then used to unclamp and remove the Clamp Head from the body upon procedure completion. In the event the Delivery Device becomes compromised during the course of a procedure, the Quick Release Device can be used to unclamp and remove the Clamp Head from the body.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

MI DeTACH® and its predicates have the same intended use, clinical setting, target user, target patient population, and principle of operation.

The MI DeTACH® uses the same principle of operation and technology as predicate devices. It is based on utilizing two clamp jaws compressing a vessel to apply sufficient forces to occlude blood flow in the vessel. The subject and predicate devices are based on the same technological elements:

- Clamp delivered through a small incision with an external handle
- Handle controls clamping force through the means of a ratchet or lever mechanism at the handle
- Soft polymer padded jaw to distribute clamping forces
- DeBakey Teeth lining the clamp to provide traction and distribute clamping forces over a larger surface area
- Clamp is detached leaving clamp in the body throughout the procedure

The following technological differences exist between the subject and the predicate device:

- DeBakey teeth are made of soft polymer and are nonmetallic
- The top jaw pivots which allow parallel closure
- Clutch safety mechanism prevents excessive clamping forces

VII. PERFORMANCE DATA

The following non-clinical testing was performed to support the substantial equivalence of the MI DeTACH® to its legally marketed predicate devices:

- Design Verification and Validation Testing
  - Design functionality testing confirms that the product meets its product requirements. The following functionality testing was conducted:
    - Vessel Occlusion Testing
    - Clamping Force Distribution Testing
    - Human Factors/Usability Studies
    - Simulated Use Testing
- Sterilization and Shelf Life
  - The Detachable Aortic Cross Clamp Head portion of the device is provided sterile with a 2-year shelf life. Product sterility, shelf life, and packaging/transport testing confirms product safety and effectiveness.
  - The Delivery System (Delivery Device and Quick Release Device) is provided non-sterile to be cleaned and sterilized at the health care facility with a 2-year or 100 cycle product life. Product cleaning, sterility, fatigue, and packaging/transport testing confirms product safety and effectiveness.
- Biocompatibility Testing
  - The biocompatibility evaluation of the MI DeTACH® was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management Process" September 4, 2020 and ISO 10993-1, "Evaluation and testing within a risk management Process" as recognized by FDA. The vascular clamp and delivery system are considered tissue contacting for a duration of less than 24 hours. Biocompatibility testing confirms that the products can be used as intended. The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogen Testing
- Hemolysis

Animal testing was not required to demonstrate the substantial equivalence of the MI DeTACH® to its predicate devices and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the MI DeTACH® to its predicate devices and is not included as part of this premarket notification.

VIII. CONCLUSION

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, MI DeTACH® is substantially equivalent to its predicate devices.