November 27, 2024

CONMED Corporation
% Robert Poggie
Pesident
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'Ile-Perrot, QC J7W3J6
Canada

Re: K242187
Trade/Device Name: BioBrace®
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWW, OWY
Dated: November 1, 2024
Received: November 4, 2024

Dear Robert Poggie:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242187

Device Name

BioBrace®

Indications for Use *(Describe)*

BioBrace® is intended for use in surgical procedures for reinforcement of soft tissue where weakness exists. BioBrace® is also intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. BioBrace® is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the repair.

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.

510(k) #: K242187

510(k) Summary

Prepared on: 2024-11-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CONMED Corporation
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Correspondent Name	BioVera, Inc.
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Correspondent Contact Telephone	(514) 349-7226
Correspondent Contact	Robert A. Poggie, PhD
Correspondent Contact Email	orthobob@biovera.ca

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BioBrace®
Common Name	Surgical mesh
Classification Name	mesh, surgical, absorbable, orthopaedics, reinforcement of tendon
Regulation Number	878.3300
Product Code(s)	OWW, OWY, FTL, QWJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203267	BioBrace®	OWW
K230316	FlexBand, FlaxPatch, FlexPlus	OWW
K222501	Regeneten Bioinductive Implant	OWY
K241906	BioBrace Reinforced Implant	OWW

Device Description Summary

21 CFR 807.92(a)(4)

The BioBrace® implant is a bioresorbable and bioinductive scaffold composed of a highly-porous collagen sponge made from insoluble bovine tendon type-1 collagen, and reinforced with poly- L-lactic-acid (PLLA) multifilament yarn (75 denier, 15 micron filament diameter). The BioBrace implant is 80% porous, average density of 0.2 grams/cm3, and median pore diameter of 19 microns. The highly-

porous collagen sponge comprises the majority of implant surface area (0.7 m2/gram) versus the PLLA filaments alone (0.2 m2/gram), creating a large biologic matrix for cellular ingrowth, tissue regeneration, and healing. BioBrace implants are approximately 3 mm thick, provided in multiple sizes, and provide for soft tissue and tendon augmentation, reinforcement, and clinically relevant strengthening of the surgical repair. The BioBrace implant is single-use and supplied sterile with SAL of 10-6.

The purpose of this 510(k) notification is to expand the indications for use for BioBrace to include extra-articular ligaments and to advise FDA of performance and in turn labeling such as 'bioinductivity', 'stiffness similar to native and repaired human tendons and ligaments', and 'clinically relevant strengthening in surgical repair'. There have been no changes to the design, manufacture, or processing of the subject device since FDA clearance of K203267, except for the addition of new sizes in K242187.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

BioBrace® is intended for use in surgical procedures for reinforcement of soft tissue where weakness exists. BioBrace® is also intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. BioBrace® is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendon, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the repair.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the subject BioBrace device and the additional predicate device (K230316) are identical except for the trade names of the devices. The indications for use for the primary predicate device, BioBrace (K203267) and additional predicate device (BioBrace Reinforced Implant, K241906) are included in the indications statement for the subject BioBrace device with the addition of specific extra articular ligaments that are part of the indications statement for the additional predicate device described in K230316.

Technological Comparison

21 CFR 807.92(a)(6)

The subject BioBrace device and primary predicate device described in K203267 are identical. There have been no changes in design, materials, manufacturing, and sterilization since BioBrace was cleared by FDA in K203267. New size options were cleared by FDA in K241906. In summary, the subject and predicate BioBrace devices are bioresorbable, bioinductive scaffolds comprised of a highly-porous collagen sponge made from insoluble bovine tendon type-1 collagen, and reinforced with poly-L-lactic-acid (PLLA) multifilament yarn. The PLLA yarn imparts tacitly sensed, clinically meaningful and relevant strength at the time of surgical repair with similar stiffness as native and repaired human tendons and ligaments. The BioBrace implant is 80% porous with median pore diameter of 19 microns, with the porous structure maintaining its open and continuous porosity under tensile load. The highly-porous collagen sponge comprises the majority of implant surface area surface that creates a large bioinductive matrix for cellular ingrowth and tissue regeneration. BioBrace implants are approximately 3 mm thick, provided in multiple sizes, and are designed for soft tissue, tendon, and extra-articular ligament augmentation, reinforcement, and strengthening of the surgical repair.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

There are two purposes for this 510K notification, the first being expansion of the indications for use for BioBrace to include extra-articular ligaments, the evidence for which was established in Q231062 and summarized in this 510(k) in the attached document 'Evidence for expanded indications for use v4'. There have been three cadaver-based laboratory studies (one published, two accepted for publication) that demonstrate strengthening of surgical repair of extra articular ligaments with BioBrace. There is one in-vivo study demonstrating bioinductivity, tissue regeneration, normal healing, and strengthening of tendon repair by BioBrace in a patella tendon defect model (central third in sheep). In addition, this 510(k) includes a company-authored review of the scientific literature showing similarity in the biology of healing of tendons and extra articular ligaments.
The second purpose of this 510(k) is new and re-worded statements of results of performance testing and analyses for BioBrace presented in K203267 and this 510(k). The evidence for bioinductivity and clinically relevant strengthening of surgical repair of soft tissues is provided in this 510(k) in several surgeon-lead and company authored papers, case reports, and technical reports of in-vivo animal studies, biomechanical and cadaver studies, and retrospective human clinical evaluations of BioBrace.
The evidence presented in this 510(k) and K203267 supports the following performance characteristics exhibited by BioBrace:

- Bioinductive / bioinductivity,
- Clinically relevant strengthening at the time of surgical repair and through the healing period,
- Stiffness similar to native and repaired human tendon and ligament tissues per mechanical testing and reference to the scientific literature,
- Maintenance of porosity and scaffold structure under tensile load and in vivo modeling of repair.

The evidence presented in this 510(k) for BioBrace demonstrates substantial equivalence to the predicate device, BioBrace (K203267) and BioBrace Reinforced Implant (K241906), and the safety and efficacy for expansion of indications for use to include extra-articular ligaments and the above statements of performance characteristics.