April 7, 2025

CONMED Corporation
Dionne Sanders
Sr. Manager, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K250395
Trade/Device Name: BioBrace ® RC Delivery System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: ORQ, OWW
Dated: February 11, 2025
Received: February 12, 2025

Dear Dionne Sanders:

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, M.S.,
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250395

Device Name

BioBrace ® RC Delivery System

Indications for Use *(Describe)*

The BioBrace® RC Delivery System is intended for use in rotator cuff surgical procedures for reinforcement of soft tissue where weakness exists. The BioBrace® Implant is intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during rotator cuff tendon repair surgery. The BioBrace® Implant is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to bone, provide mechanical strength for the tendon repair.

The Disposable Inserter is intended to facilitate the delivery and positioning of the implant during soft tissue repairs.

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
BioBrace® RC Delivery System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, CONMED Corporation is hereby submitting the 510(k) Summary for 510(k) Number K250395.

I. SUBMITTER

Manufacturer:
CONMED Corporation
525 French Road
Utica, NY 13502

Official Contact Person:
Dionne Sanders, JM, MS, CQA, RAC
525 French Road
Utica, NY 13502
(O) 813-205-7536

Date Prepared: April 4, 2025

II. DEVICE NAME

Proposed Device	BioBrace® RC Delivery System
Common Name:	Mesh, Surgical, Deployer
Establishment Registration No.:	1320894
Regulatory Class:	Class II, per 21 CFR 878.3300
Review Panel:	Orthopedics
Classification Name:	Surgical Mesh
Product Code:	ORQ, OWW

III. PREDICATE DEVICE

Trade/Device Name:	The BioBrace™ Implant
Proprietary Name:	Reinforced implant
Establishment Registration No.	1320894
Review Panel:	Orthopedics
Regulation Number:	21 CFR 878.3300
Common/Regulation Name:	Surgical Mesh
Regulatory Class:	Class II
Product Code:	OWW, OWY
510K#:	K241906

IV. DEVICE DESCRIPTION

The BioBrace® RC Delivery System is comprised of a BioBrace® Implant pre-stitched with HI-FI® suture, a threader assembly that facilitates passing sutures through the BioBrace® Implant, and an inserter to facilitate placement of the BioBrace® Implant into the subacromial space.

The previously cleared BioBrace® Implant is a bioresorbable, reinforced Implant 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. The BioBrace® Implant is 80% porous with a median pore diameter of 19 µm. BioBrace® implants are approximately 3 mm thick and provided in two rectangular sizes of 23 x 25 mm and 35 x 25 mm.

The BioBrace® RC Delivery System is single-use and supplied sterile (ETO).

V. INTENDED USE/ INDICATIONS FOR USE

The BioBrace® RC Delivery System is intended for use in rotator cuff surgical procedures for reinforcement of soft tissue where weakness exists. The BioBrace® Implant is intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during rotator cuff tendon repair surgery. The BioBrace® Implant is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to bone, provide mechanical strength for the tendon repair.

The Disposable Inserter is intended to facilitate the delivery and positioning of the implant during soft tissue repairs.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed Device	**Predicate Device**
Manufacturer Device Name 510k Number	K250395	CONMED Corporation BioBrace® Reinforced Implant K241906
Intended Use/ Indications for Use	The BioBrace® RC Delivery System is intended for use in rotator cuff surgical procedures for reinforcement of soft tissue where weakness exists. The BioBrace® Implant is intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during rotator cuff tendon repair	The BioBrace Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The BioBrace Implant is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or

	surgery. The BioBrace® Implant is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to bone, provide mechanical strength for the tendon repair. The Disposable Inserter is intended to facilitate the delivery and positioning of the implant during soft tissue repairs.	quadriceps tendons. The BioBrace Implant is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to bone, provide mechanical strength for the tendon repair.
Contraindications	Same	The BioBrace alone is not indicated for ligament repair or reconstruction. The BioBrace is not indicated for use in patients with known history of hypersensitivity to bovine-derived materials.
How Supplied	Same	Sterile
Single Use /Reusable	Same	Single-Use Only
Sterilization	Same	Ethylene Oxide Sterilization achieving a SAL (10^{-6})
Shelf-Life	12 months	6 months
Biocompatibility	Same	In accordance with ISO 10993-1
Packaging	Temperature label, folding carton, tray, pouch, eIFU insert, patient implant card.	Temperature label, retention box kit, pouch, envelope shelf box, packaging insert card, eIFU insert, patient implant card.
Base Material	75 denier multi filament PLLA yarn, collagen, PEG 400	
Physical form / Porosity	Porous mesh / scaffold - 80%	
PLLA Properties	Peak Melting Temperature, PLLA ©: 178 – 184°C Inherent Viscosity, PLLA (dL/g):1.20 – 1.70 dL/g	
Sizes	23X25mm 35X25mm	23X25mm 35X25mm 40X60mm
Bioresorbable	Yes	
Deployer	Yes	No

VII. PERFORMANCE DATA

Testing and analysis have been completed to demonstrate that BioBrace® RC Delivery System performs as intended and is substantially equivalent to the predicate device.

- Biocompatibility
- Packaging
- Packaging and Labeling User Validation
- Performance Testing
- Shelf-life
- Sterilization
- Transportation
- User Validation

VIII. CONCLUSION

The proposed and the predicate devices have similar intended use, indications for use, technological characteristics and mechanisms of operation. The addition of a sterile disposable, deployer instrument to facilitate delivery of the implant does not pose any new issues of safety or efficacy. Testing for the proposed device demonstrated performance effectiveness, and safety similar to the predicate device. The BioBrace® RC Delivery System is substantially equivalent to the predicate BioBrace™ Reinforced Implant (K241906).