October 15, 2025

CONMED Corporation
Amy Delong
Regulatory Affairs Associate
525 French Road
Utica, New York 13502

Re: K252946
Trade/Device Name: BioBrace® Extra-Articular Ligament Augmentation Kit
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, OWY, OWW
Dated: September 13, 2025
Received: September 15, 2025

Dear Amy Delong:

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,

Thomas Mcnamara -S

For: 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252946 |

Please provide the device trade name(s).

BioBrace® Extra-Articular Ligament Augmentation Kit

Please provide your Indications for Use below.

The BioBrace® Extra-Articular Ligament Augmentation Kit is intended to reattach soft tissue to bone and reinforce soft tissue where weakness exists in extra-articular knee ligament surgical procedures.

The Argo Knotless® GENESYS™ Anchor may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

The BioBrace® Reinforced BioInductive Implant is intended for reinforcement of soft tissues that are repaired by suture or suture anchors during knee repair surgery including reinforcement of patellar ligament, medial collateral ligament, lateral collateral ligament or other knee extra-articular ligaments. It is not intended to replace normal body structures or provide the full mechanical strength to the repair. 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY
BioBrace® Extra-Articular Ligament Augmentation Kit

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 K252946.

## I. SUBMITTER

Manufacturer:
CONMED Corporation
525 French Road
Utica, NY 13502

Official Contact Person:
Amy DeLong
525 French Road
Utica, NY 13502
(O) (908) 488-5893

Date Prepared: October 15, 2025

## II. DEVICE NAME

| | |
|---|---|
| Proposed Device: | BioBrace® Extra-Articular Ligament Augmentation Kit |
| Common Name: | Fastener, fixation, biodegradable, soft tissue<br>Mesh, surgical, absorbable, orthopaedics, reinforcement of tendon<br>Mesh, surgical, collagen, orthopaedics, reinforcement of tendon |
| Establishment Registration No.: | 1320894 |
| Regulatory Class: | Class II,<br>21 CFR 888.3030<br>21 CFR 878.3300 |
| Review Panel: | Orthopedics |
| Classification Name: | Single/multiple component metallic bone fixation appliance and accessories<br>Surgical Mesh |
| Product Code: | MAI, OWW, OWY |

## III. PREDICATE DEVICES

| | |
|---|---|
| 510K#: | K244025 |
| Device: | Argo Knotless® ™Anchor |
| Common Name: | Fastener, fixation, biodegradable, soft tissue |
| Regulatory Class: | Class II,<br>21 CFR 888.3030<br>21 CFR 888.3040 |
| Review Panel: | Orthopedics |

| | |
|---|---|
| Classification Name: | Single/multiple component metallic bone fixation appliance and accessories |
| Product Code: | MAI, MBI |

Additional Predicate:

| | |
|---|---|
| 510K#: | K240090 |
| Device:Argo Knotless® Anchor | |
| Common Name: | Fastener, fixation, biodegradable, soft tissue |
| Regulatory Class: Class II, | 21 CFR 888.3030<br>21 CFR 888.3040 |
| Review Panel: | Orthopedics |
| Classification Name: | Single/multiple component metallic bone fixation appliance and accessories |
| Product Code: | MAI, MBI |

Additional Predicate:

| | |
|---|---|
| 510K#: | K242187 |
| Device: BioBrace® | |
| Common Name: | Surgical Mesh |
| Regulatory Class: Class II, | 21 CFR 878.3300 |
| Classification Name: | Surgical Mesh |
| Product Code: | OWW, OWY |

Reference Device:

| | |
|---|---|
| Trade/Device Name: | CuffLink™ Implant System (Biocomposite) |
| Proprietary Name: | CuffLink |
| Establishment Registration No.: | 1320894 |
| Review Panel: | Orthopedics |
| Regulation Number: | 21 CFR 888.3030 |
| Regulation Name: | Single/multiple component metallic bone fixation appliances and accessories |
| Regulatory Class: | Class II |
| Product Code: | MAI, MBI |
| 510K#: | K180763 |

## IV. DEVICE DESCRIPTION

The BioBrace® Extra-Articular Ligament Augmentation Kit is a single-use augmentation procedure kit for use in general surgical procedures for BioBrace® Reinforced BioInductive Implant ("BioBrace® implant") reinforcement of soft tissue where weakness exists, specifically in the extra-articular knee ligaments.

The kit is comprised of bioabsorbable implants and instrumentation. The kit includes one (1) tapered BioBrace Implant 5x250mm, which is threaded through the anchor eyelet.

Kit components are assembled in a single PETG tray and retainer then sealed in a Tyvek pouch. The BioBrace® Extra-Articular Ligament Augmentation Kit is supplied sterile (ETO).

Identical to K240090
Argo Knotless® GENESYS ™ Anchor: The Non-Self-Punching Argo Knotless® GENESYS™ Anchor is an implantable bone anchor, that is supplied single use, sterilized via ethylene oxide (ETO) to a SAL of $10^{-6}$. The anchor configuration requires a pre-prepared bone hole. The threaded anchor is manufactured of bioabsorbable material, and the suture eyelet is manufactured of PEEK material. Each size features a single use driver, a threaded anchor, a PEEK suture eyelet, a #2 UHMWPE, non-absorbable retention suture, and loader tab. The retention suture holds the PEEK eyelet in place on the driver and can be incorporated into the repair if desired. The suture eyelet can hold up to six (6) sutures. These anchor configurations require a pre-prepared bone hole which can be created with Class I, Exempt instrumentation.

Identical to K244025
Argo Knotless® GENESYS ™ Anchor: The Argo Knotless® GENESYS™ Anchor is an implantable bone anchor, that is supplied single use, sterilized via ethylene oxide (ETO) to a SAL of $10^{-6}$. The threaded anchor is manufactured of bioabsorbable material, and the suture eyelet is manufactured of PEEK Optima material. The device features a single use driver, a threaded anchor, a PEEK-Optima eyelet, a #2 UHMWPE, non-absorbable retention suture, and loader tab. The retention suture holds the PEEK eyelet in place on the driver and can be incorporated into the repair if desired. The suture eyelet can hold up to six (6) sutures or one (1) bioresorbable reinforced implant. These anchor configurations require a pre-prepared bone hole which can be created with Class I, Exempt instrumentation.

Identical to K242187
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.

## V. INTENDED USE/ INDICATIONS FOR USE

The BioBrace® Extra-Articular Ligament Augmentation Kit is intended to reattach soft tissue to bone and reinforce soft tissue where weakness exists in extra-articular knee ligament surgical procedures.

The Argo Knotless® GENESYS™ Anchor may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments,

tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

The BioBrace® Reinforced BioInductive Implant is intended for reinforcement of soft tissues that are repaired by suture or suture anchors during knee repair surgery including reinforcement of patellar ligament, medial collateral ligament, lateral collateral ligament or other knee extra-articular ligaments. It is not intended to replace normal body structures or provide the full mechanical strength to the repair. 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.

## VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| | **Proposed Device** | **Predicate Device** | **Reference Device** |
|---|---|---|---|
| **Manufacturer**<br>**Device Name**<br><br>**510k Number** | **BioBrace® Extra-Articular Ligament Augmentation Kit**<br><br>**K252946** | **K244025 - Primary**<br>**K240090 - Additional**<br>**K242187 - Additional** | **CONMED Corporation**<br>**CuffLink™ Implant System (Biocomposite)**<br><br>**K180763** |
| Intended Use/ Indications for Use | The BioBrace® Extra-Articular Ligament Augmentation Kit is intended to reattach soft tissue to bone and reinforce soft tissue where weakness exists in extra-articular knee ligament surgical procedures.<br><br>The Argo Knotless® GENESYS™ Anchor may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.<br><br>The BioBrace® Reinforced BioInductive Implant is intended for reinforcement of soft tissues | **K244025, K240090**<br>The biocomposite suture anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures.<br><br>The Argo Knotless® GENESYS™ Anchor may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.<br><br>**K242187**<br><br>The BioBrace® Reinforced BioInductive Implant is intended | The Implant System may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization,<br>throughout the healing period.<br>INDICATIONS FOR USE<br>The CuffLink™ Implant System Biocomposite is indicated to reattach soft tissue to bone in the following orthopedic<br>surgical procedures.<br>Procedures:<br>Rotator cuff repair/Shoulder<br>Achilles Repair/Ankle |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| **Manufacturer Device Name**<br><br>**510k Number** | **BioBrace® Extra-Articular Ligament Augmentation Kit**<br><br>**K252946** | **K244025 - Primary**<br>**K240090 - Additional**<br>**K242187 - Additional** | **CONMED Corporation**<br>**CuffLink™ Implant System (Biocomposite)**<br><br>**K180763** |
| | that are repaired by suture or suture anchors during knee repair surgery including reinforcement of patellar ligament, medial collateral ligament, lateral collateral ligament or other knee extra-articular ligaments. It is not intended to replace normal body structures or provide the full mechanical strength to the repair. 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. | for reinforcement of soft tissues that are repaired by suture or suture anchors during knee repair surgery including reinforcement of patellar ligament, medial collateral ligament, lateral collateral ligament or other knee extra-articular ligaments. It is not intended to replace normal body structures or provide the full mechanical strength to the repair. 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 | 1. Pathological conditions of bone which would adversely affect the BioBrace® Extra-Articular Ligament Augmentation Kit.<br>2. Pathological conditions in the soft tissue to be repaired or reconstructed which would | **K244025**<br>1. Pathological conditions of bone which would adversely affect the Argo Knotless® GENESYS™ Anchor.<br>2. Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation. | 1. Pathological conditions of bone which would adversely affect the CuffLink™ Implant System (Biocomposite).<br>2. Pathological conditions in the soft tissue to be repaired or reconstructed which would adversely affect suture fixation.<br>3. Physical conditions that would eliminate, or tend to eliminate, |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| **Manufacturer Device Name**<br><br>**510k Number** | **BioBrace® Extra-Articular Ligament Augmentation Kit**<br><br>**K252946** | **K244025 - Primary**<br>**K240090 - Additional**<br>**K242187 - Additional** | **CONMED Corporation**<br>**CuffLink™ Implant System (Biocomposite)**<br><br>**K180763** |
| | adversely affect suture fixation.<br>3. Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing.<br>4. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.<br>5. Direct attachment of artificial ligaments or other implants except for bioresorbable reinforced implants.<br>6. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials.<br>7. This device is not approved for screw attachment or fixation to the posterior elements | 3. Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing.<br>4. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.<br>5. Direct attachment of artificial ligaments or other implants except for bioresorbable reinforced implants.<br>6. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials.<br>7. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. | adequate implant support or retard healing.<br>4. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.<br>5. Attachment of artificial ligaments or other implants.<br>6. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials.<br>7. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| **Manufacturer Device Name**<br><br>**510k Number** | **BioBrace® Extra-Articular Ligament Augmentation Kit**<br><br>**K252946** | **K244025 - Primary**<br>**K240090 - Additional**<br>**K242187 - Additional** | **CONMED Corporation CuffLink™ Implant System (Biocomposite)**<br><br>**K180763** |
| | (pedicles) of the cervical, thoracic or lumbar spine.<br>8. Patients with insufficient quality or quantity of bone for drilling.<br>9. Patients with active sepsis or infection.<br>10. The BioBrace® Extra-Articular Ligament Augmentation Kit is not indicated for use in patients with known history of hypersensitivity to bovine-derived materials. | | |
| Principle of Operation | Absorbable suture anchor for soft tissue to bone fixation. For use with a resorbable reinforcement implant. | **K244025**<br>Absorbable suture anchor for soft tissue to bone fixation. For use with a resorbable reinforcement implant. | Absorbable suture anchor for soft tissue to bone fixation |
| How Supplied | Sterile Kit (implants, instrumentation) | Sterile Anchor on a delivery driver | Sterile Kit (implants, instrumentation) |
| Single Use / Reusable | Single-Use Only | Single-Use Only | Single-Use Only |
| Performance Data Testing | • Post-Transportation Functional Testing<br>• Transportation Conditioning testing | **Argo Knotless Genesys Anchor (K244025)**<br>• User Validation | •Biocompatibility<br>•Packaging (Transportation and Shelf-life)<br>•Sterilization |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| **Manufacturer Device Name**<br><br>**510k Number** | **BioBrace® Extra-Articular Ligament Augmentation Kit**<br><br>**K252946** | **K244025 - Primary**<br>**K240090 - Additional**<br>**K242187 - Additional** | **CONMED Corporation CuffLink™ Implant System (Biocomposite)**<br><br>**K180763** |
| | • Biocompatibility<br>• Packaging (Transportation and Shelf-Life)<br>• Packaging and Labeling User Validation<br>• Sterilization<br>• User Validation<br>• Packaging and Labeling User Validation<br>• LAL Pyrogen Test | • Packaging and Labeling User Validation<br><br>**Argo Knotless Genesys Anchors (K240090)**<br>• Performance testing<br>• Transportation<br>• Shelf-life<br>• Biocompatibilty<br>• Packaging (Transportation and shelf-life)<br>• Sterilization<br>• User Validation Packaging and Labeling User Validation<br>• Pyrogen test plan<br>• Degradation<br><br>**BioBrace Reinforced Bioinductive Implant (K242187)**<br>• Animal study<br>• Biocompatibility<br>• Degradation | •User Validation<br>•Packaging and Labeling User Validation<br>•Pyrogenicity |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| **Manufacturer Device Name**<br><br>**510k Number** | **BioBrace® Extra-Articular Ligament Augmentation Kit**<br><br>**K252946** | **K244025 - Primary**<br>**K240090 - Additional**<br>**K242187 - Additional** | **CONMED Corporation CuffLink™ Implant System (Biocomposite)**<br><br>**K180763** |
| | | • Physical, Mechanical and Material characterization<br>• Sterilization<br>• Pyrogen Testing<br>• Packaging<br>• Shelf-life | |
| Sterilization | Ethylene Oxide Sterilization achieving a SAL ($10^{-6}$) | Ethylene Oxide Sterilization achieving a SAL ($10^{-6}$) | Ethylene Oxide Sterilization achieving a SAL ($10^{-6}$) |
| Shelf-Life | 6 months | Argo Genesys Anchors – 18 months<br>BioBrace Implant – 24 months | 36 months |
| Biocompatibility | In accordance with ISO 10993-1 | In accordance with ISO 10993-1 | In accordance with ISO 10993-1 |
| Material | Bioabsorbable | Bioabsorbable | Bioabsorbable |
| Packaging | The new kit is similar to reference device, but adds temperature and tamper evident labels. | Individually packaged devices | Kit tray/retainer, pouch, folding carton, eIFU insert, patient implant card (PIC), shipping carton |
| Kit Configuration | Three (3) implants, four (4) instruments | N/A - sold as individual devices | Four (4) implants, two (2) instruments |

## VII. PERFORMANCE DATA

Testing and analysis have been completed to demonstrate that BioBrace® Extra-Articular Ligament Augmentation Kit performs as intended and is substantially equivalent to the predicate devices.

- Post-Transportation Functional Testing
- Transportation Conditioning testing
- Biocompatibility
- Packaging (Transportation and Shelf-Life)
- Packaging and Labeling User Validation
- Sterilization
- User Validation
- Packaging and Labeling User Validation
- LAL Pyrogen Testing

## VIII. CONCLUSION

The proposed and the predicate devices have similar intended use, indications for use, technological characteristics and mechanisms of operation of the devices per their initial clearance. The BioBrace® Extra-Articular Ligament Augmentation Kit is substantially equivalent to the predicate devices.