January 13, 2026

Miach Orthopaedics, Inc.
℅ Julie Broderick
Regulatory Consultant
Broderick Regulatory Consulting, LLC
7 Kendall Street
Winchester, Massachusetts 01890

Re: K251214
Trade/Device Name: BEAR® (Bridge-Enhanced ACL Restoration) Implant
Regulation Number: 21 CFR 888.3044
Regulation Name: Resorbable Implant For Anterior Cruciate Ligament (ACL) Repair
Regulatory Class: Class II
Product Code: QNI
Dated: December 10, 2025
Received: December 10, 2025

Dear Julie Broderick:

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.

510(k) Number *(if known)*
K251214

Device Name
BEAR® (Bridge-Enhanced ACL Restoration) Implant

Indications for Use *(Describe)*
The BEAR® (Bridge-Enhanced ACL Restoration) Implant is a bovine extracellular matrix collagen-based implant for treatment of anterior cruciate ligament (ACL) injuries. The BEAR® Implant is indicated for adults, adolescents and children with a complete or partial rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair. Children with open physes must have sufficient bone in the femoral and tibial epiphyses on either side of the intended tunnel locations to avoid disruption of the growth plates.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. Submitter Information

Company: Miach Orthopaedics, Inc.
69 Milk Street, Suite 100
Westborough, MA 01581 USA
Phone No.: 800-590-6995
Fax No.: 508-986-9625

Contact: Rita Paparazzo
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Miach Orthopaedics, Inc.
Phone No.: 800-590-6995
Email: rpaparazzo@miachortho.com

Date Prepared: 8 January 2026

II. Name of Device

Device Trade Name: BEAR® (Bridge-Enhanced ACL Restoration) Implant
Classification Name: Resorbable implant for anterior cruciate ligament (ACL) repair
Product Code: QNI
Regulation Number: 21 CFR 888.3044
Device Class: II
Panel Identification: Orthopedics

III. Predicate Device

Predicate Manufacturer: Miach Orthopaedics, Inc.
Predicate Trade Name: BEAR® (Bridge-Enhanced ACL Restoration) Implant
Predicate 510(k) No.: K243578

IV. Device Description

The BEAR® Implant (nominal 22 mm in diameter and 44 mm in length) is cylindrical in shape and comprised of collagen and extracellular matrix derived from bovine connective tissue, which has been cleaned, disinfected and processed by a proprietary manufacturing method. The implant has been terminally sterilized by electron-beam irradiation and is intended to be used with up to 10 ml of autologous blood drawn during the surgical implantation procedure. The BEAR® Implant stabilizes the blood in the gap between the tom ligament ends. The BEAR® Implant is resorbed within 8 weeks and replaced with a fibrovascular repair tissue.

V. Indications for Use

The BEAR® (Bridge-Enhanced ACL Restoration) Implant is a bovine extracellular matrix collagen-based implant for treatment of anterior cruciate ligament (ACL) injuries. The BEAR® Implant is indicated for adults,

adolescents and children with a complete or partial rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair. Children with open physes must have sufficient bone in the femoral and tibial epiphyses on either side of the intended tunnel locations to avoid disruption of the growth plates.

VI. Comparison of Technological Characteristics

Characteristic	**New Device** **BEAR Implant**	**Predicate Device*** **BEAR Implant** **K243578**	**Comparison**
Manufacturer	Miach Orthopaedics, Inc.	Miach Orthopaedics, Inc.	Same
Regulation No.	21 CFR 888.3044	21 CFR 888.3044	Same
Regulation Name	Resorbable implant for anterior cruciate ligament (ACL) repair	Resorbable implant for anterior cruciate ligament (ACL) repair	Same
Regulatory Class	Class II	Class II	Same
Product Classification Code	QNI	QNI	Same
Intended Use / Indications for Use	The BEAR® (Bridge-Enhanced ACL Restoration) Implant is a bovine extracellular matrix collagen-based implant for treatment of anterior cruciate ligament (ACL) injuries. The BEAR® Implant is indicated for adults, adolescents and children with a complete or partial rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair. Children with open physes must have sufficient bone in the femoral and tibial epiphyses on either side of the intended tunnel locations to avoid disruption of the growth plates.	The BEAR® (Bridge-Enhanced ACL Restoration) Implant is a bovine extracellular matrix collagen-based implant for treatment of anterior cruciate ligament (ACL) injuries. The BEAR® Implant is indicated for adults, adolescents and children with a complete or partial rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair. Children with open physes must have sufficient bone in the femoral and tibial epiphyses on either side of the intended tunnel locations to avoid disruption of the growth plates.	Same
Device Description	The BEAR Implant (22 mm in diameter and 44mm in length) is cylindrical in shape and comprised of collagen and extracellular matrix derived from bovine connective tissue, which has been cleaned, disinfected and processed by a proprietary manufacturing method. The implant is intended to be used with up to 10 ml of autologous blood drawn during the surgical implantation procedure.	The BEAR Implant (22 mm in diameter and 44mm in length) is cylindrical in shape and comprised of collagen and extracellular matrix derived from bovine connective tissue, which has been cleaned, disinfected and processed by a proprietary manufacturing method. The implant is intended to be used with up to 10 ml of autologous blood drawn during	Same

Characteristic	New Device BEAR Implant	Predicate Device* BEAR Implant K243578	Comparison
		the surgical implantation procedure.	
Operating Principle	The BEAR Implant stabilizes the blood in the gap between the torn ligament ends, facilitating restoration of the ACL. The BEAR Implant is resorbed within 8 weeks and replaced with a fibrovascular repair tissue.	The BEAR Implant stabilizes the blood in the gap between the torn ligament ends, facilitating restoration of the ACL. The BEAR Implant is resorbed within 8 weeks and replaced with a fibrovascular repair tissue.	Same
Materials	Bovine-derived Type 1 collagen and extracellular matrix	Bovine-derived Type 1 collagen and extracellular matrix	Same – no changes
Biocompatibility	No new testing required	Testing completed per ISO 10993-1 and FDA guidance	Same – no changes
Technical Specifications	No new testing required	As approved in DEN200035 and referred to in K243578	Same – no changes
In Vivo Animal Testing	No new animal testing required; existing published animal data support the reduced OA claim.	Completed as described in DEN200035 and referred to in K243578	Addition of claim to labeling did not require new animal testing to validate. Existing published animal data support the reduced OA claim.
Human Clinical Testing	Supporting clinical data presented in 510(k)	BEAR II Study (see DEN200035); referred to in K243578	De Novo approval based on BEAR II (G150268) and BEAR I (G140151) study data; this 510(k) includes supporting clinical data from long-term follow-up of the same studies concerning the lower rate of post-traumatic radiographic (KL grade ≥2) osteoarthritis of the knee at Year 6 in BEAR subjects compared to ACLR control subject.

VII. Performance or Clinical Testing

No non-clinical or animal performance testing was required to support this 510(k), as the change was limited to the addition of an OA[1] claim to the labeling and there were no changes to the design or specifications of the BEAR Implant. Published animal data established the potential for the BEAR Implant to reduce post-traumatic knee OA following ACL transection in a porcine model:

[1] In this 510(k) the acronym "OA" refers to post-traumatic radiographic osteoarthritis (Kellgren-Lawrence grade ≥2) of the knee.

- Murray MM, Fleming BC. Use of a bioactive scaffold to stimulate anterior cruciate ligament healing also minimizes posttraumatic osteoarthritis after surgery. Am J Sports Med. 2013;41(8):1762-1770.
- Kiapour AM, Fleming BC, Murray MM. Structural and anatomic restoration of the anterior cruciate ligament Is associated with less cartilage damage 1 year after surgery: healing ligament properties affect cartilage damage. Orthop J Sports Med. 2017;5(8): 2325967117723886.

Clinical testing demonstrated a reduced rate of OA at 6-years post-surgery, as compared to the ACLR control group, which received primarily hamstring tendon autograft, supporting the additional claim of reduced risk of post-traumatic knee OA following the BEAR procedure as compared to ACLR. OA data were collected in two clinical studies, as follows:

	BEAR I Feasibility Study	**BEAR II Pivotal Study**
Level of Evidence	Non-randomized study with concurrent ("active") control	Randomized, multi-arm, "blinded" study with concurrent ("active") control
Location of Study	United States only	United States only
IDE No.	G140151	G150268
Primary Safety Endpoint	Multiple safety endpoints, including rates of: • Deep joint infection/incision and drainage of deep surgical site infection • Graft rejection/removal • Graft/repair failure, as defined in protocol • Any additional adverse events including (but not limited to) deep venous thrombosis, loss of function, need for prolonged parenteral pain medication, development of neurologic symptoms or additional trauma • Any additional surgical procedures that the patient requires on the operative knee, as well as any surgical procedures required on the contralateral knee • Presence of bovine type I gelatin IgE antibodies	
Primary Effectiveness Endpoint	• Co-primary effectiveness endpoints ▪ International Knee Documentation Committee (IKDC) [Subjective] score at 24 months post-surgery; and ▪ Instrumented [KT-1000] AP laxity of the knee at 24 months post-surgery	
Osteoarthritis Endpoints	• Primary: Kellgren Lawrence grade ≥ 2 at 6 years post-surgery • Secondary: Overall KL grade (mean and proportion of subjects), MOAKS and joint space width (JSW), all at 6 years post-surgery	

- Patient Accountability:

Stage	Investigational Device (BEAR Implant) Arm Total	Control (ACLR) Arm Total	Total
BEAR I			
Enrollment	10	10	20
Treatment (Surgery)	10	10	20
Primary Safety Endpoint Analysis	9	7	16
Primary Effectiveness Endpoint Analysis	9	7	16
OA Analysis at 6-Years Post-Surgery	7	6	13
BEAR II			
Enrollment	73	36	113
Treatment (Surgery)	65	35	100
Primary Safety Endpoint Analysis	65	35	100
Primary Effectiveness Endpoint Analysis	65	35	100
OA Analysis at 6-Years Post-Surgery	46	21	67

- The BEAR II Study met its primary endpoints. Refer to the Decision Summary for DEN200035 for details of the safety and effectiveness endpoints.
- Results of OA analyses demonstrated a statistically significant reduction (-27.7% [95% CI: -46.9%, -10.1%], p=0.002, one-sided alpha = 0.025) in the rate of OA at 6-years post-surgery in the pooled (BEAR I + BEAR II) BEAR arm compared to the pooled ACLR control arm.
- The primary and secondary outcomes of the BEAR II study were similar for subjects with 6-year OA data when compared to the overall BEAR II analysis upon which DEN200035 was based.
- There were no statistically significant differences in adverse events between treatment arms at Year 6 post-index procedure.
- As established in DEN200035 and K243578, the BEAR Implant is as safe and as effective as ACLR, and the BEAR Implant subject of this 510(k) is identical to and therefore as safe and as effective as the BEAR Implant cleared in K243578. This 510(k) supports the claim of reduced OA at 6-years in patients treated with the BEAR Implant compared to those treated with ACLR.

VIII. Special Controls

The BEAR Implant subject of this 510(k) meets the Special Controls established for “Resorbable implant for anterior cruciate ligament (ACL) repair”, product classification code QNI, classification regulation 21 CFR 888.3044.

IX. Conclusions

Miach Orthopaedics concludes that the BEAR Implant is substantially equivalent to its predicate, the BEAR Implant cleared in K243578 and does not raise any new issues or concerns of safety or effectiveness. The

BEAR Implant demonstrates reduced OA at 6-years compared to ACLR using hamstring tendon autograft as described in the text added to the Clinical Summary section of the Instructions for Use:

> *In patients 14 years and older who have an ACL injury with concomitant knee injuries, ACL restoration with the BEAR Implant reduces the risk of developing post-traumatic knee osteoarthritis (Kellgren-Lawrence grade 2 or higher), at 6-years post-surgery, compared to ACL reconstruction (ACLR) surgery using hamstring tendon autograft.*