March 6, 2025

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

Re: K243578
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: February 5, 2025
Received: February 5, 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, MS
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)*

K243578

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.

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.
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Westborough, MA 01581 USA
Phone No.: 800-590-6995
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Date Prepared: 5 February 2025

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.: DEN200035

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.

Children with open physes must have sufficient bone in the femoral and tibial epiphyses to accommodate a 2.4 mm cannulated drill pin with at least 2-3 mm of bone on either side of the intended tunnel locations to avoid disruption of the growth plates.

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** **DEN200035**	**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 skeletally-mature patients at least 14 years of age with a complete rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair.	Same except for changes in Indications: - Remove age limitation (≥14 years) - Remove requirement for patient to be skeletally mature - Replace both with “adults, adolescents and children” - Add requirement for epiphyseal bone in children to avoid disruption of growth plates - Add partial rupture of ACL Same Intended Use; both new and predicate devices are intended for use in treating ACL injuries.
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 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	Same

Characteristic	New Device BEAR Implant	Predicate Device* BEAR Implant DEN200035	Comparison
	the surgical implantation procedure.	autologous blood drawn during 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	Same – no changes
In Vivo Animal Testing	No new animal testing required	Completed as described in DEN200035	Changes to Indications did not require new animal testing to validate.
Human Clinical Testing	Confirmatory clinical data presented in **eSTAR Section: Performance Testing**	BEAR II Study (see DEN200035)	De Novo approval based on BEAR II study data; this 510(k) includes confirmatory clinical data from the BEAR III study (G170156) and the BRIDGE Registry (post-market study).

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 indications for use.

Confirmatory clinical data from the BEAR III Study (IDE #G170156) and the BRIDGE Registry (post-market study) demonstrated that the BEAR Implant subject of this 510(k) is as safe and effective as the predicate device in patients less than 14 years of age and in patients with partial ACL tears.

The BEAR III Study was a prospective multicenter single-arm cohort study of the BEAR Implant that enrolled 151 subjects at 7 U.S. investigational sites. The study eligibility criteria included subjects ≥12 years of age and with partial or complete ACL tears. The two primary outcomes were the IKDC Subjective Knee Evaluation score and IKDC Objective Physical Exam score at post-operative year 2. Safety endpoints included the rate of adverse events (AE), serious adverse events (SAE), UADEs and device-related AEs and SAEs.

The ongoing BRIDGE Registry is a real-world observational registry, with prospective and retrospective arms, of patients receiving the BEAR Implant at up to 30 U.S. sites. The two primary effectiveness endpoints are

IKDC Subjective Knee Evaluation score at year 2 and Lachman knee laxity at 1 year. Secondary endpoints include 7 patient-reported outcomes (PRO) and knee-related adverse events.

For purposes of this 510(k) submission, safety and effectiveness data for BEAR Implant patients under age 14 were compared to those ≥14 years from the pooled BEAR III and BRIDGE studies were analyzed; safety and effectiveness data for patients with partial ACL tears were compared to complete ACL tears using the BEAR III dataset alone. Refer to **Table 1** for subject accountability by age group and **Table 2** for subject accountability by tear type.

Table 1: Subject Accountability by Age Group

	Baseline	**Surgery**	**1 Year**	**2 Years**
Visit Completed, Subjects **≥ 14** Years Old, BEAR III	167	148	136	89
Visit Completed, Subjects **<14** Years Old, BEAR III	3	3	3	2
Visit Completed, Subjects **<14** Years Old, BRIDGE Registry [1]	14	15	7	6
[1] Includes the proportion of subjects who have an EDC entry for either IKDC, current status questionnaire, or physical exam at that timepoint EXCLUDING where all assessments were marked as not done.				

Table 2: Subject Accountability by Tear Type

	Baseline	**Surgery**	**1 Year**	**2 Years**
Visit Completed, Subjects with **complete** tear, BEAR III	124	124	114	79
Visit Completed, Subjects with **partial** tear, BEAR III	27	27	25	12
[1] Includes the proportion of subjects who have an EDC entry for either IKDC, current status questionnaire, or physical exam at that timepoint EXCLUDING where all assessments were marked as not done.				

Of the 18 subjects under 14 years of age, the mean age was 12.4 ± 1.98 years with a range from 7.7 to 14.0 years, 61.1% were white, 33.3% Black, 5.6% Asian and 11.2% other/refused, and 6.3% were Hispanic/Latino. Of the 27 subjects with a partial tear, 81.5% were white, 7.4% Black, 7.4% Asian, 3.7% Native Hawaiian or Pacific Islander, and 11.2% other/refused, and 18.5% were Hispanic/Latino.

The analyses supporting this label change were pre-specified in a prospective statistical analysis plan (SAP).

Safety & Effectiveness by Age

IKDC was compared between subjects <14 years and subjects ≥14 years in a non-inferiority analysis, whereas knee laxity was assessed descriptively, as were AE/SAE data. At 1 and 2 years post-op, subjects <14 years had on average higher IKDC scores than subjects ≥14 years, demonstrating a non-inferior outcome between the

two age groups. A similar outcome was seen in the Lachman knee laxity test. AEs were analyzed in three age groups, <14 years, 14-18 years and 19+ years. Subjects in the youngest age group (<14 years) experienced rates of AEs, serious adverse events (SAE), and device-related AEs and SAEs that were similar to the oldest subjects (19+ years) and lower than 14–18-year-olds.

Safety & Effectiveness by Tear Type

There were no differences in effectiveness outcomes (IKDC Subjective, IKDC Physical Exam, Lachman) or safety between subjects with partial ACL tears at baseline and those with complete ACL tears.

In conclusion, the BEAR Implant is as safe and effective in patients under 14 years of age as those over 14 years and as safe and effective in patients with partial ACL tears as those with complete ACL tears. Furthermore, only slight modifications to the BEAR procedure are required to address these patient populations, and no data from this analysis suggest that those surgical modifications are difficult or present new or increased risks to the BEAR procedure. These data support the substantial equivalence of the BEAR Implant subject of this 510(k) with the predicate BEAR Implant.

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 authorized in DEN200035, and does not raise any new issues or concerns of safety or effectiveness.