December 16, 2020

Miach Orthopaedics, Inc.
% Julie N. Broderick, RAC
Principal Consultant
Broderick Regulatory Consulting, LLC
P.O. Box 903
Winchester, Massachusetts 01890

Re: DEN200035
Trade/Device Name: BEAR® (Bridge-Enhanced ACL Repair) 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: June 3, 2020
Received: June 4, 2020

Dear Ms. Broderick:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the BEAR® (Bridge-Enhanced ACL Repair) Implant, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The BEAR® (Bridge Enhanced ACL Repair) 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the BEAR® (Bridge-Enhanced ACL Repair) Implant, and substantially equivalent devices of this generic type, into Class II under the generic name resorbable implant for anterior cruciate ligament (ACL) repair.

FDA identifies this generic type of device as:

> **Resorbable implant for anterior cruciate ligament (ACL) repair**. A resorbable implant for anterior cruciate ligament (ACL) repair is a degradable material that allows for healing of a torn ACL that is biomechanically stabilized by traditional suturing procedures. The device is intended to protect the biological healing process from the surrounding intraarticular environment and not intended to replace biomechanical fixation via suturing. This classification includes devices that bridge or surround the torn ends of a ruptured ACL.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 4, 2020, FDA received your De Novo requesting classification of the BEAR® (Bridge-Enhanced ACL Repair) Implant. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BEAR® (Bridge-Enhanced ACL Repair) Implant into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the BEAR® (Bridge-Enhanced ACL Repair) Implant can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Repaired ACL has inadequate durability, leading to re-tear	Animal testing Clinical performance testing Labeling
Repaired ACL is loose or functionally limited, leading to joint instability	Clinical performance testing
ACL does not heal due to inadequate resorption or migration of implant	Non-clinical performance testing Animal testing
Adverse tissue reaction	Biocompatibility evaluation Labeling
Infection	Sterilization validation Shelf life testing Labeling
Febrile response due to endotoxins	Pyrogenicity testing
Implant is incompatible with other ACL repair instrumentation and sutures, leading to inability to complete surgery	Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the resorbable implant for anterior cruciate ligament (ACL) repair is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    (i) Post-operative evaluation of knee pain and function; and
    (ii) Durability as assessed by re-tear or re-operation rate.
(2) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    (i) Device performance characteristics, including resorption and ligament healing at repair site; and
    (ii) Adverse effects as assessed by gross necropsy and histopathology.
(3) Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    (i) Characterization of materials, including chemical composition, resorption profile, and mechanical properties; and
    (ii) Simulated use testing, including device preparation, device handling, compatibility with other ACL repair instrumentation, and user interface.
(4) The device must be demonstrated to be biocompatible.
(5) Performance data must demonstrate the device to be sterile and non-pyrogenic.
(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
(7) Labeling must include the following:
    (i) Identification of device materials and specifications;
    (ii) A summary of the clinical performance testing conducted with the device;
    (iii) Instructions for use, including compatibility with other ACL repair instrumentation or devices;
    (iv) Warnings regarding post-operative rehabilitation requirements; and
    (v) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the resorbable implant for anterior cruciate ligament (ACL) repair they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Pooja Panigrahi, Ph.D., at 240-402-1090.

Sincerely,

Raquel A. Peat -S3

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health