April 8, 2022

Embody, Inc.
Brianna Schehr
Director of Quality, Regulatory & Clinical Affairs
4211 Monarch Way, Suite 500
Norfolk, Virginia 23508

Re: K213958
Trade/Device Name: Bioabsorbable Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: March 10, 2022
Received: March 10, 2022

Dear Brianna Schehr:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laura C. Rose, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213958

Device Name
Bioabsorbable Anchor

Indications for Use *(Describe)*
The Bioabsorbable Anchor is indicated for the fixation of soft tissue grafts in various minimally invasive and open orthopedic surgical procedures in shoulder.

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.

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K213958 – 510(k) Summary

I. SUBMITTER

Owner/Submitter:	Embody, Inc. 4211 Monarch Way Suite 500 Norfolk, VA 23508
Phone:	236-994-7912
Contact Person:	Brianna Schehr Director of Quality, Regulatory & Clinical Affairs
Date Prepared:	April 8, 2022

II. DEVICE

Name of Device:	Bioabsorbable Anchor
Common or Usual Name:	Bone Anchor
Classification Name:	Fastener, fixation, biodegradable, soft tissue
Regulation Number:	21 CFR 888.3030
Regulatory Class:	Class II
Product Code:	MAI
Medical Specialty:	Orthopedic

III. PREDICATE DEVICE

Rotation Medical Bone Staple (RMB Staple), K131635. This predicate has not been subject to a design-related recall.

ORTHOSORB Resorbable Pins, K111077, is being referenced as a device made of polydioxanone. Therefore, the use of polydioxanone as a fixation material is not new.

IV. DEVICE DESCRIPTION

The Bioabsorbable Anchor is an absorbable implant device that is intended to provide fixation of a prosthetic material to soft tissue and/or bone. The Bioabsorbable Anchor is composed of polydioxanone (PDO) dyed with D&C Violet No. 2. Two Bioabsorbable Anchors are provided sterile for single use only, packaged preloaded in a disposable anchor inserter instrument, the Dual Anchor Inserter. The preloaded Dual Anchor Inserter is provided in a dual sterile pouch configuration.

V. INDICATION FOR USE

The Bioabsorbable Anchor is indicated for the fixation of soft tissue grafts in various minimally invasive and open orthopedic surgical procedures in shoulder.

Both the subject and predicate devices have the same intended use for the fixation of a prosthetic material.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Bioabsorbable Anchor is substantially equivalent in terms of indications for use, technological characteristics, and performance characteristics to the predicate device. Fixation is the technological principle for both the subject and predicate devices and is based on the use of a permanent implant in a U-shape polymer strap design with barbed ends, to directly affix a prosthetic material. The Bioabsorbable Anchor is substantially equivalent to the reference device in terms of material composition of an absorbable fixation device.

The following technological differences exist between the subject and predicate devices:

- The subject device is composed of an absorbable polymer (polydioxanone), whereas the predicate device is a nonabsorbable polymer (PEEK), and
- The subject device is optimized for fixation to both soft tissue and bone, whereas the predicate device is optimized only for fixation to bone.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing
The biocompatibility evaluation for the Bioabsorbable Anchor device was conducted in accordance with the FDA guidance document “Use of International Standard ISO 10993-1, ‘Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process’” dated September 4, 2020, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation Testing Within a Risk Management Process,” as recognized by FDA. The final, finished device met the requirements of the standards for the following battery of tests: cytotoxicity, sensitization, irritation, acute systemic toxicity, systemic toxicity (material-mediated pyrogenicity), bacterial endotoxin testing, genotoxicity, and implantation. Chemical characterization in accordance with ISO 10993-18 and a toxicological risk assessment in accordance with ISO 10993-17 confirmed the Bioabsorbable Anchor is considered safe for its intended use.

The Bioabsorbable Anchor is considered a permanent implant device in contact with tissue/bone, while the anchor inserter instrument is considered tissue/bone contacting for a duration of less than 24 hours.

Non-Clinical Performance Testing
The Bioabsorbable Anchor was evaluated in comparison to the predicate device when applicable in accordance with the FDA guidance document “Bone Anchors—Premarket Notification (510(k)) Submissions” and included the following tests:

- Insertion Testing
- Pullout Testing
- Fatigue Testing

Both the subject and predicate devices had suitable characteristics for their indication for use.

A sixteen-week *in vitro* hydrolytic degradation study guided by ASTM F1635-16 “Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants” was also performed. This study provided characterization of the degradation profile via mass loss.

Absorption Profile
The Bioabsorbable Anchor is hydrolytically degraded in tissues and demonstrated expected local tissue response, histological observations, and degradation after 13 weeks in both intramuscular and femoral condyle implantation. The degradation products are subsequently absorbed by tissues and excreted from the body.

VIII. CONCLUSIONS

Results of the biocompatibility testing and non-clinical performance testing demonstrate that the Bioabsorbable Anchor is as safe and as effective, and substantially equivalent to the predicate device for its intended use.