June 2, 2023

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

Re: K223822
Trade/Device Name: Activbraid™
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable polyethylene terephthalate surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: December 21, 2022
Received: December 21, 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,

Cynthia Chang -S

Cynthia J. Chang, Ph.D.
Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K223822

Device Name
ACTIVBRAID™

Indications for Use *(Describe)*
ACTIVBRAID™ is indicated for use in soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.

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.

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510(k) Summary – K223822

I. SUBMITTER

Owner/Submitter:	Embody, Inc. 4211 Monarch Way Suite 500 Norfolk, VA 23508
Phone:	236-994-7912
Contact Person:	Brianna Schehr Vice President, Quality, Regulatory & Clinical Affairs
Date Prepared:	May 24, 2023

II. DEVICE

Name of Device:	ACTIVBRAID™
Common or Usual Name:	Suture
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Regulation Number:	21 CFR 878.5000
Regulatory Class:	Class II
Product Code:	GAT
Medical Specialty:	General & Plastic Surgery

III. PREDICATE DEVICE

Arthrex Bio-Suture, K112899. This predicate has not been subject to a design-related recall.

Reference Devices: Arthrex BioWire, K091018
ORTHOCORD® Braided Composite Suture, K040004

IV. DEVICE DESCRIPTION

ACTIVBRAID is a partially absorbable surgical co-braid suture constructed of nonabsorbable Ultra High Molecular Weight Polyethylene (UHMWPE) and absorbable bovine-derived type I collagen. ACTIVBRAID suture ends are stiffened with cyanoacrylate.

ACTIVBRAID is available in several sizes (sutures meet U.S. Pharmacopeia standards for nonabsorbable sutures, except diameter). Sutures are oversized in diameter. ACTIVBRAID is provided in pre-cut lengths with and without needles. Suture strands that are dyed (Chromium Cobalt-Aluminum Oxide or D&C Black No. 4) are made of UHMWPE.

V. INDICATION FOR USE

ACTIVBRAID is indicated for use in soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ACTIVBRAID is substantially equivalent in terms of indication for use, technological characteristics, and performance characteristics to the predicate device. Both the subject and predicate devices meet the USP Monograph for nonabsorbable surgical sutures, except diameter.

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

- The subject device is composed of nonabsorbable UHMWPE fiber braided with absorbable bovine type I collagen fiber, whereas the predicate device is composed of nonabsorbable UHMWPE fiber braided with polyester fibers coated with absorbable type I bovine collagen, and
- The subject device is available in sizes 2-0, 2, 1.5mm tape, and 2.5mm tape, whereas the predicate device is available in sizes 2 and 2mm tape.

The differences between the subject and predicate device are considered minor and do not raise questions concerning safety and effectiveness. Biocompatibility and nonclinical performance testing data demonstrate that ACTIVBRAID is as safe, as effective, and performs as well as or better than the predicate device, K112899.

VII. PERFORMANCE DATA

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

Biocompatibility Testing
The biocompatibility evaluation for the ACTIVBRAID 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 battery of testing included the following tests: cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, genotoxicity, and implantation.

Non-Clinical Performance Testing
Nonclinical performance testing was performed to demonstrate that ACTIVBRAID meets the current USP Monograph for nonabsorbable surgical sutures, except diameter. Testing was performed in accordance with FDA's guidance document, "Surgical Sutures – Class II Special Controls Guidance Document for Industry and FDA Staff" and included the following tests:

- Nonabsorbable Suture Diameter USP *<861> Sutures – Diameter*
- Nonabsorbable Suture Needle Attachment USP *<871> Sutures – Needle Attachment*
- Nonabsorbable Suture Tensile Strength USP *<881> Sutures – Tensile Strength*

ACTIVBRAID meets or exceeds USP performance standards for nonabsorbable surgical sutures, except for an oversize in diameter. Bacterial Endotoxin Test (BET) was performed to demonstrate that the subject device meets pyrogen limit specifications.

Additional performance testing was conducted in comparison to the predicate device and included the following tests:

- Abraded Tensile Strength
- Knot Profile
- Knot Security
- Abrasiveness to Tissue
- Physiological Fluid Absorption

ACTIVBRAID performs as well as or better than the predicate device for all performance tests listed. Both the subject and predicate devices have suitable characteristics for their indication for use.

Resorption Profile

ACTIVBRAID is partially absorbable; therefore, resorption profile testing was conducted in accordance with FDA's special controls guidance, "Surgical Sutures – Class II Special Controls Guidance Document for Industry and FDA Staff" to characterize the device's rate of absorption, time to complete absorption, and residual tensile strength over time. The results of implantation studies of ACTIVBRAID in animals indicate that approximately 85% of its original strength remains 16 weeks after implantation and absorption of the collagen component is complete between 8 and 16 weeks post-implantation. The ACTIVBRAID degradation profile combined with the tensile strength retention over time demonstrates the resorption profile is consistent with the intended use of the subject device, for the long-term approximation of soft tissue.

Substantial Equivalence

Characteristic	Subject Device	Predicate Device Arthrex Bio-Suture (K112899)	Comparison
Product Code	GAT	GAT	Same
Regulation	21 CFR 878.5000	21 CFR 878.5000	Same
Classification Name	Suture, Nonabsorbable, Synthetic, Polyethylene	Suture, Nonabsorbable, Synthetic, Polyethylene	Same
Intended Use	Long-term approximation of soft tissue	Long-term approximation of soft tissue	Same
Indications for Use	For use in soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.	For use in soft tissue approximation and/or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.	Same
Prescription Use	Yes	Yes	Same
Material(s) of Composition	UHMWPE, bovine-derived type I collagen	UHMWPE, polyester, bovine-derived type I collagen	Similar, no new issues of safety or efficacy
Resorbable	Partially absorbable (i.e., nonabsorbable UHMWPE fiber and absorbable collagen fiber co-braid)	Nonabsorbable (i.e., nonabsorbable braided UHMWPE and polyester fibers coated with absorbable type I bovine collagen)	Similar, no new issues of safety or efficacy

Characteristic	Subject Device	Predicate Device Arthrex Bio-Suture (K112899)	Comparison
Suture Configuration(s)	Configured as multifilament braided strands of multiple sizes (per USP size system) ACTIVBRAID suture: • Size 2-0 (blue) w/ tapered needle • Size 2 (blue) w/ tapered needle • Size 2 (white/black) w/ tapered needle ACTIVBRAID suture tape: • Flat, tape-style suture, 1.5mm (white/black) w/ tapered needle • Flat, tape-style suture, 1.5mm (blue) w/ tapered needle • Flat, tape-style suture, 2.5mm (white/black) • Flat, tape-style suture, 2.5mm (blue)	Configured as multifilament braided strands of multiple sizes (per USP size system) Bio-FiberWire: • Size 2 (blue) w/ tapered needle Bio-FiberTape: • Flat, tape-style suture, 2mm (blue)	Similar, no new issues of safety or efficacy
Residual Tensile Strength Over Time	85% of original strength remains 16 weeks after implantation	Not known to have significant change in tensile strength *in vivo*	Similar, no new issues of safety or efficacy
Technological Principle	Long-term approximation of soft tissue	Long-term approximation of soft tissue	Same
Operating Principles	Standard surgical technique	Standard surgical technique	Same
How Supplied	Sterile, single use only, with or without needles attached	Sterile, single use only, with or without needles attached	Same
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Single Use	Single Use	Single Use	Same

VIII. CONCLUSIONS

Results of the biocompatibility testing and nonclinical performance testing demonstrate that ACTIVBRAID is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K112899.