May 23, 2022

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

Re: K220867
Trade/Device Name: TAPESTRY® Biointegrative Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY
Dated: April 11, 2022
Received: April 12, 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)*

K220867

Device Name
TAPESTRY® Biointegrative Implant

Indications for Use *(Describe)*
TAPESTRY® Biointegrative Implant is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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

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 Embody, Inc. Phone: +1 (236) 994-7912 Email: bschehr@embody-inc.com
Date Prepared:	May 19, 2022

II. DEVICE

Name of Device:	TAPESTRY® Biointegrative Implant
Common or Usual Name:	Tendon Protector
Classification Name:	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement of Tendon
Regulation Number:	21 CFR 878.3300
Regulatory Class:	Class II
Product Code:	OWY
Medical Specialty:	General & Plastic Surgery

III. PREDICATE DEVICE

TAPESTRY® Biointegrative Implant, K212306. This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The TAPESTRY® Biointegrative Implant is composed of collagen and poly(D,L-lactide). It is designed to function as a non-constricting, protective layer between the tendon and surrounding tissues. The implant is provided sterile for single use only. It is supplied as a standalone implant, in an insertion sleeve, or on an introducer. The introducer assists in delivering the implant to the surgical site during arthroscopic procedures. The device is provided in a dual pouch configuration.

V. INDICATION FOR USE

TAPESTRY® Biointegrative Implant is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same intended use, indication for use, and fundamental scientific technology as the predicate device. The subject device is the same TAPESTRY® Biointegrative Implant as the predicate device, with the exception that an implant introducer will be included with three currently offered (and within the cleared size range) sizes of the predicate device. The introducer assists in delivering the TAPESTRY® Biointegrative Implant to the surgical site during arthroscopic procedures.

VII. PERFORMANCE DATA

A risk analysis was conducted for the design change (i.e., the new introducer instrument) and to identify the verification and validation activities necessary to mitigate any identified risks and establish substantial equivalence. Performance testing submitted to support this change included: introducer functional design verification testing (cannula passage, introducer release, stopper pressure test), simulated-use validation testing in an arthroscopic cadaver model, sterilization validation, and shelf-life testing. A battery of biocompatibility testing was conducted and included the following tests: cytotoxicity, sensitization, irritation, system toxicity, and pyrogenicity. Results of the performance testing demonstrated the device functions as intended and appropriate for its intended use and is substantially equivalent to the predicate. The testing in this submission was directly applicable to the new introducer and no additional performance testing was required for the implant based on the modification.

VIII. CONCLUSIONS

The TAPESTRY® Biointegrative Implant subject device is the same device as its predicate except it is provided on an introducer. The device modification does not raise any different questions of safety or efficacy. The TAPESTRY® Biointegrative Implant subject device is substantially equivalent to the TAPESTRY® Biointegrative Implant predicate device.