November 2, 2021

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

Re: K212306
Trade/Device Name: Tapestry Biointegrative Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY
Dated: September 29, 2021
Received: September 30, 2021

Dear Ms. 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,

for Deborah Fellhauer, RN, BSN
Acting Assistant 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)*
K212306

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.

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510(k) SUMMARY

Device Trade Name: TAPESTRY® Biointegrative Implant

Device Common Name: Tendon Protector

Device Class: II

Classification Name: Mesh, Surgical

Regulation No.: 878.3300

Product Code: OWY

Predicate Device: TAPESTRY® Biointegrative Implant, K201572

Owner/Submitter: Embody, Inc.

4211 Monarch Way, Suite 500
Norfolk, VA 23508
(757) 777-5674

Regulatory Contact: Brianna Schehr
Director of Regulatory Affairs
Email: bschehr@embody-inc.com
Telephone: (236) 994-7912

Date Prepared: September 29, 2021

DEVICE DESCRIPTION

The TAPESTRY® Biointegrative Implant (TAPESTRY) 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. TAPESTRY is conformable and designed for easy placement between the tendon and surrounding tissue and may be secured in place using standard fixation techniques. TAPESTRY is provided sterile, non-pyrogenic, for single-use only, in a variety of sizes, ranging from 20mm x 25mm to 70mm x 50mm. TAPESTRY is available with or without a co-packaged polyethylene Insertion Sleeve, which is used to maintain the implant's orientation and to facilitate easy application onto the tendon. The Insertion Sleeve is discarded after use and not implanted. TAPESTRY is designed for stand-alone use. At the discretion of the surgeon, TAPESTRY may be hydrated with sterile isotonic solution.

Preclinical studies of TAPESTRY showed dense collagenous fibrous connective tissue ingrowth into and around the scaffolding.

INTENDED USE/INDICATIONS FOR USE

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

SUBSTANTIAL EQUIVALENCE SUMMARY

TAPESTRY is the same device as its TAPESTRY predicate, with the same indications for use, design, materials, and technological characteristics and, therefore is substantially equivalent. Validation methods for establishing collagen stability throughout TAPESTRY's shelf life has been added to support expansion of the shelf life of the subject device. Two new product size/shape offerings, within the originally cleared size range, have been added based on user feedback.

SUMMARY OF PERFORMANCE TESTING

TAPESTRY is the same device as its predicate, TAPESTRY (K201572), in regard to all aspects of the device. Only the collagen stability validation method changed between the current device and the predicate device. Past performance testing (safety, biocompatibility, bench) of the predicate device is directly applicable to the subject device. Additional tests to confirm the collagen stability of the device were performed. Hydroxyproline analysis was conducted to confirm the collagen quantity and Fourier Transform Infrared (FTIR) analysis was conducted to confirm collagen quality. Together with the product stability testing of the predicate device, the collagen stability testing will be used to support expansion of the shelf life of the subject device. No new performance testing was required to support the additional product sizes, as the sizes are within the cleared size range and the cleared labeling allows for trimming of the device. The performance testing demonstrates that TAPESTRY is substantially equivalent to the predicate device.

CONCLUSION

The purpose of this 510(k) application was to notify the Food and Drug Administration of the new validation methods for establishing collagen stability throughout TAPESTRY's shelf life. TAPESTRY is the same device as the TAPESTRY device cleared under K201572 with the same intended use, design, and technological characteristics. The new collagen stability validation methods do not raise any different questions of safety or efficacy. Therefore, the TAPESTRY subject device is substantially equivalent to the TAPESTRY predicate device.