August 16, 2021

Embody, Inc.
% Scott Bruder
CEO, Bruder Consulting and Venture Group
Bruder Consulting and Venture Group
4211 Monarch Way, Ste. 500
Norfolk, Virginia 23508

Re: K201572
Trade/Device Name: TAPESTRY Biointegrative Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWY

Dear Mr. Bruder:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 19, 2020. Specifically, FDA is updating this SE Letter as an administrative correction to the product codes removing FTM as a secondary product code.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Deborah Fellhauer, OHT4: Office of Surgical and Infection Control Devices, Deborah.Fellhauer@fda.hhs.gov.

Sincerely,

Min Zhang -S

for Deborah Fellhauer
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

October 19, 2020

Embody, Inc.
% Scott Bruder
CEO, Bruder Consulting and Venture Group
Bruder Consulting and Venture Group
4211 Monarch Way, Ste. 500
Norfolk, Virginia 23508

Re: K201572
Trade/Device Name: TAPESTRY Biointegrative Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, FTM
Dated: June 10, 2020
Received: June 11, 2020

Dear Dr. Bruder:

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,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201572

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	Rotation Medical Inc. Collagen Tendon Sheet, K112423
Reference Device:	Surgi Wrap MAST Tendon Sheet, K063648
Owner/Submitter:	Embody, Inc. 4211 Monarch Way, Suite 500 Norfolk, VA 23508 (757) 777-5674
Regulatory Contact:	Scott Bruder, MD, PhD Founder and CEO, Bruder Consulting & Venture Group scott@bruderconsulting.com Tele: 201.874.9701
Date Prepared:	October 13, 2020

DEVICE DESCRIPTION

The TAPESTRY® Biointegrative Implant device 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.

SUMMARY/COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

TAPESTRY® and its predicate have the same intended use/indications for use, and basic similarities in design, materials, and technological characteristics and are substantially equivalent. A comparison of the subject and predicate device are provided in the table below.

haracteristic	Subject Device Embody TAPESTRY®	Predicate Device Rotation Medical Collagen Tendon Sheet
Material Composition	Highly aligned composite implant (70% PDLLA, 30% type I bovine collagen) non crosslinked	Highly oriented implant, (100% type I bovine collagen), crosslinked
Form	Resorbable flat sheet	Resorbable flat sheet
Color/ Appearance	White to off white with blue orientation lines on unaligned side	White to off white with a blue perimeter
Size	Multiple sizes from 2.0cm x 2.5cm to 7.0cm x 5.0cm	1.5x2cm, 2x2.5cm,2.5x3cm
Density	Low (<0.016g/cm^3)	Low (0.3g/cm^3)
Porosity/Void Fraction	>85% porosity	85–90% porosity
Intraoperative Characteristics	Open and laparoscopic/endoscopic and arthroscopic procedures. Can be sutured	Open and laparoscopic/endoscopic and arthroscopic procedures. Can be sutured
Pyrogenicity	Non-pyrogenic (< 1 EU/device)	Non-pyrogenic (< 0.5 EU/ml)
Sterilization Method	Electron Beam to SAL of 10^{-6}	Ethylene Oxide to SAL of 10^{-6}
Single Use /Reuse	Single use only	Single use only
How Supplied	Dry packaged in a high-barrier, double foil pouch with secondary sterile barrier	Lyophilized, packaged in sterile packaging
Storage Conditions	Room temperature/ambient	Room temperature/ambient

TAPESTRY® and its predicate have been characterized for chemical composition, purity, density, porosity, and strength to demonstrate substantial equivalence. Testing was conducted in accordance with to FDA's *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh*.

Biocompatibility Testing for TAPESTRY® including, cytotoxicity, sensitization, intracutaneous irritation, systemic toxicity, pyrogenicity, and genotoxicity satisfied the requirements outlined in ISO 10993-1 *Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process,* and helped demonstrate that the device is substantially equivalent to its predicate and is biocompatible in accordance to ISO 10993-1.

The *in vivo* animal study evaluated local tissue response, systemic toxicity, and the device resorption profile in a clinically relevant tendon model. TAPESTRY® was found to be completely resorbed between the 52 to 72-week time points with a complete quiescence of the associated inflammatory response. The device was shown to yield favorable results in the calcaneal tendon incision model and supports a determination of substantial equivalence.

REFERENCE DEVICE

The Surgi-Wrap MAST Tendon Sheet is a legally marketed device that has additional applicability for establishing substantial equivalence, having the same intended use and composed of poly(D,L-lactide.

CONCLUSION

The results of the mechanical performance, biocompatibility and animal efficacy testing demonstrated that TAPESTRY® is substantially equivalent to its predicate.