September 19, 2025

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

Re: K252647
Trade/Device Name: Tapestry Biointegrative Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY
Dated: August 21, 2025
Received: August 21, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252647

Please provide the device trade name(s).

Tapestry Biointegrative Implant

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. SUBMITTER

Owner/Submitter:	Embody, Inc. 4211 Monarch Way Suite 500 Norfolk, VA 23508
Phone:	+1 (778) 444-7197
Contact Person:	Brianna Schehr Associate Director, Regulatory Affairs Embody, Inc. Phone: +1 (778) 444-7197 email: brianna.schehr@zimmerbiomet.com
Date Prepared:	September 19, 2025

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 or in an insertion sleeve to maintain the implant orientation and facilitate easy application, or on an introducer to facilitate arthroscopic delivery. 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

A change was made to the subject device to broaden the specifications for density and thickness. No other changes were made to the subject device. The subject device has the same intended use, indication for use, and fundamental scientific technology as the predicate device. The differences in density and thickness between the subject and predicate device are considered minor and do not raise questions concerning safety and effectiveness. The non-clinical test results demonstrate that the

predetermined acceptance criteria used to support the predicate device were met for the subject device and that the changes to the density and thickness do not alter the device's safety and effectiveness profile.

VII. PERFORMANCE DATA

A risk analysis was conducted for the design change and to identify the verification and validation activities necessary to mitigate any identified risks and establish substantial equivalence. Identified non-clinical testing was conducted and results were substantially equivalent to the prior non-clinical testing. Non-clinical testing included mechanical (tensile strength and suture retention strength) testing and porosity analysis.

VIII. CONCLUSIONS

The Tapestry Biointegrative Implant subject device compared to the predicate device does not raise any different questions of safety or effectiveness. The Tapestry Biointegrative Implant subject device is substantially equivalent to the Tapestry Biointegrative Implant predicate device and is as safe and effective as the legally marketed predicate device.