October 2, 2024

Collagen Matrix, Inc.
Devin Dragon
Sr. Regulatory Specialist
15 Thornton Road
Oakland, New Jersey 07436

Re: K242302
Trade/Device Name: RejuvaKnee™ Collagen Meniscus Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OLC
Dated: August 2, 2024
Received: August 5, 2024

Dear Devin Dragon:

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, MS
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)*
K242302

Device Name

RejuvaKnee™ Collagen Meniscus Implant

Indications for Use *(Describe)*

RejuvaKnee is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the RejuvaKnee must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

RejuvaKnee reinforces soft tissue and provides a reasonable scaffold that is replaced by the patient's own soft tissue. The RejuvaKnee is not a prosthetic device and is not intended to replace normal body structure.

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.

510(k) SUMMARY

1. Applicant Information

Applicant Name: Collagen Matrix, Inc.
Address: 15 Thornton Road
Oakland, New Jersey 07436
Telephone: (201) 405-1477
Fax: (201) 405-1355

Contact Person: Devin Dragon
Sr. Regulatory Specialist
ddragon@regenity.com

Date Prepared: September 30, 2024

2. Name of the Device

Device Trade Name: RejuvaKnee™ Collagen Meniscus Implant
K242302

Device Common Name(s): Scaffold, Partial Medial Meniscal Defects Extending into the Red/White Zone, Resorbable Bovine Collagen

Device Classification Name: Surgical Mesh
878.3300
OLC
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device: Collagen Meniscus Implant
Stryker Endoscopy
(originally Ivy Sports Medicine, LLC)
K170364

4. Description of the Device

The RejuvaKnee™ Collagen Meniscus Implant is comprised primarily of bovine Type I collagen (nominally 99%) derived from meniscus. The device is provided in a semi-lunar shape with a triangular cross section to be used to reinforce weakened soft tissue and provide a resorbable scaffold that is replaced by the patient's own tissue.

RejuvaKnee is supplied sterile and is intended for single use.

5. Intended Use

RejuvaKnee is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the RejuvaKnee must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

RejuvaKnee reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The RejuvaKnee is not a prosthetic device and is not intended to replace normal body structure.

6. Summary/Comparison of Technical Characteristics

The subject device and predicate device have the same indications for use. The subject device has substantially equivalent technological characteristics as the predicate device. Differences in tissue source are minimized after processing and purification.

Feature	RejuvaKnee™ Collagen Meniscus Implant (This submission)	Ivy Sports Medicine Collagen Meniscus Implant From Stryker Endoscopy
Indications for Use	RejuvaKnee is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for RejuvaKnee must extend at least into the red/white zone of the meniscus to provide sufficient vascularization. RejuvaKnee reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The RejuvaKnee is not a prosthetic device and is not intended to replace normal body structure.	The Collagen Meniscus Implant (CMI) is intended for use in surgical procedures for the reinforcement and repair of soft tissue injuries of the medial meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CMI must extend at least into the red/white zone of the meniscus to provide sufficient vascularization. The CMI reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CMI is not a prosthetic device and is not intended to replace normal body structure.
Chemical and Physical Properties		
Material Composition	Primarily Type I bovine collagen	Type I bovine collagen
Material Origin	Bovine	Bovine
Tissue Source	Meniscus	Deep flexor Achilles tendon
Physical Form	Semi-lunar shape with a triangular cross-section	Semi-lunar shape with a triangular cross-section
Product Sizes (cm)	Small Medial – 7.5 mm Large Medial – 9 mm	Small Medial – 7.5 mm Large Medial – 9 mm XL Medial
Porosity - SEM of the outer and cross-section (not regular testing)	Provides sufficient porosity to allow for cellular integration from host tissue >5 micron	Provides sufficient porosity to allow for cellular integration from host tissue
pH	6 - 9.5	7.12
Tensile Strength (kg/cm^2)	≥ 150	62.5
Suturability (kg)	≥ 0.5	0.86 ±0.08

Feature	RejuvaKnee™ Collagen Meniscus Implant (This submission)	Ivy Sports Medicine Collagen Meniscus Implant From Stryker Endoscopy
Thermal Stability (°C)	60 ± 3	61±1
Biocompatibility	Meets ISO 10993 biocompatibility series of testing	Biocompatible
Sterility	Sterile, SAL 10-6 using Gamma irradiation	Sterile, SAL 10-6 using Gamma irradiation
Pyrogenicity	Non-pyrogenic - <0.5EU/ml and ≤20.0EU/device	Non-pyrogenic - <0.5EU/ml and ≤20.0EU/device
Single Use/ Reuse	Single use only	Single use only

7. Performance Data

In vivo and *in vitro* testing of the subject device was conducted to demonstrate substantial equivalence of the subject device to its predicate device. The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with the testing matrix of ISO 10993-1.

Bench Testing

Collagen characterization testing and product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate. Testing included dimensions, porosity, pH, tensile strength, suturability, pyrogenicity and thermal stability. Each lot of finished devices is tested for bacterial endotoxin for lot release.

Animal Testing

The performance of the device in goat and canine models confirmed that RejuvaKnee is safe, biocompatible and associated with meniscus defect tissue repair and remodeling, and provides the necessary medial condyle support and biomechanics to prevent secondary joint changes resulting from an untreated partial meniscectomy. The performance in the canine model was compared to the published performance of the predicate device and confirmed equivalent performance.

Clinical Studies

Clinical performance of the RejuvaKnee™ Collagen Meniscus Implant subject device was evaluated in a simulated clinical setting to demonstrate that the RejuvaKnee maybe successfully implanted equivalent to the predicate device. The subject device is the same device type, has the same intended use, design, and bovine-derived collagen safety profile as the predicate device. Based on the equivalent material and performance specifications, and equivalent principle of operation to the predicate device, clinical studies of the subject device are not needed to support substantial equivalence.

8. Conclusions Drawn from Non-clinical Studies

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to its predicate device.