DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 2, 2017

Ivy Sports Medicine, LLC
John Dichiara
Senior Director of Regulatory and Clinical
545 Penobscot Drive
Redwood City, California 94063

Re: K170364
Trade/Device Name: Ivy Sports Medicine Collagen Meniscus Implant XL (CMI XL)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OLC
Dated: January 27, 2017
Received: February 6, 2017

Dear Mr. Dichiara:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170364

Device Name
Ivy Sports Medicine Collagen Meniscus Implant XL (CMI XL)

Indications for Use *(Describe)*
The Ivy Sports Medicine 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.

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.

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SECTION 6

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K170364

Applicant Information:

Owner Name: Ivy Sports Medicine, LLC
Address: 545 Penobscot Drive
Redwood City, CA 94063
Main Phone: 650-562-0800
Fax: 650-562-0808

Establishment Registration Number: 2956141

Contact Person: John Dichiara
Phone: 917-439-2597
Fax: 650-562-0808

Date Prepared: January 27, 2017

Device Information:

Classification: Class II

Trade Name: Collagen Meniscus Implant XL (CMI XL)

Common name: Surgical Mesh

Classification name: Scaffold, Partial Medial Meniscal Defects Extending into the Red/White Zone, Resorbable Bovine Collagen

Regulation number: 21 CFR §878.3300

Product Code: OLC

Predicate Device:

The Collagen Meniscus Implant XL is substantially equivalent in Intended Use, Fundamental Scientific Technology and Performance to the following legally marketed device in commercial distribution: ReGen Collagen Scaffold Surgical Mesh cleared

under K082079 (Also known as the ReGen CS and the Ivy Sports Medicine Collagen Meniscus Implant (CMI)).

Device Description:

The Ivy Sports Medicine Collagen Meniscus Implant XL (CMI XL) is a resorbable collagen matrix comprised primarily of bovine type I collagen. The CMI 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. The surgeon trims the device to the size necessary for repair of the damaged or weakened soft tissue. The CMI XL is provided sterile for single use only.

Intended Use:

The Ivy Sports Medicine 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.

Comparison to Predicate Device(s):

The CMI XL has the same intended use and technological characteristics as the predicate device, ReGen Collagen Scaffold, with the exception of the physical dimensions and mass. Any differences identified do not raise new questions of safety or effectiveness, as supported by appropriate testing.

Technological Characteristics/Performance Data:

The Collagen Meniscus Implant XL is substantially equivalent to the predicate device in intended use, fundamental scientific technology, and performance specifications. Design verification testing was performed to verify that the performance of the Collagen Meniscus Implant XL remains substantially equivalent to the predicate device. Testing performed on the Collagen Meniscus Implant XL demonstrated that all of the pre-determined acceptance criteria were met with passing results.

Clinical Testing:

Clinical evaluation is not required for this device. The product has the same material composition, fundamental scientific technology, shape and performance specifications. The only difference between the CMI XL and the predicate is that the overall height dimension is approximately 12.5% greater than the predicate to better match the height of the native meniscus rim in patients where the existing two sizes of the CS device do not meet the surgeon and patient needs.

Substantial equivalence:

The Collagen Meniscus Implant XL has the following similarities to the ReGen Collagen Scaffold predicate device cleared under K082079.

- has the same intended use and indication for use;
- has the same technological characteristics;
- has the same principles of operation;
- has equivalent performance characteristics; and
- has the same sterilization process.

Summary

In summary, the Collagen Meniscus Implant XL, the subject of this submission, is as safe and effective as the ReGen Collagen Scaffold. It has the same indication for use, the same principles of operation and the same technological characteristics as the ReGen Collagen Scaffold. The differences between the Collagen Meniscus Implant XL and the ReGen Collagen Scaffold raise no new issues of safety or effectiveness. Bench performance test data demonstrate that the Collagen Meniscus Implant XL is as safe and effective as the ReGen Collagen Scaffold and is therefore substantially equivalent to the predicate device.