DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 14, 2016

Ivy Sports Medicine, LLC
Mr. John Dichiara
Senior Vice President
Quality Assurance, Clinical and Regulatory Affairs
545 Penobscot Drive
Redwood City, California 94063

Re: K153087
Trade/Device Name: Ivyair Meniscus System, Curved, Ivyair Meniscus System, Straight, Ivyair Meniscus System, Reverse Curved
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: October 21, 2015
Received: October 26, 2015

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 yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5

INDICATIONS FOR USE

510(k) Number (if known): K153087

Device Name: IvyAIR Meniscus System

Indications for Use:

The IvyAIR Meniscus System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The IvyAIR Meniscus System is indicated for use in meniscal repairs and allograft transplant procedures. The IvyAIR Meniscus System device is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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: K

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:	October 21, 2015

Device Information:

Classification:	Class II
Trade Name:	IvyAIR Meniscus System
Common name:	Meniscus Repair Device
Classification name:	Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulation number:	21 CFR §878.5000
Product Code:	GAT

Predicate Device:

The IvyAIR Meniscus System is substantially equivalent in Intended Use, Fundamental Scientific Technology and Performance to the following legally marketed device in commercial distribution: Smith & Nephew FAST-FIX 360 Meniscal Repair System cleared under K121861.

Device Description:

The IvyAIR Meniscus System is an all-inside meniscus repair device. Each device includes two non-absorbable polymer implants, pre-tied with 2-0 non-absorbable suture and pre-loaded into a needle delivery system. The IvyAIR System is available in three needle configurations: Curved, Straight and Reverse Curve to allow the surgeon a choice for access to the desired zone of the meniscus. The IvyAIR Meniscus System is provided sterile for single use only.

Intended Use:

The IvyAIR Meniscus System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The IvyAIR Meniscus System is indicated for use in meniscal repairs and allograft transplant procedures. The IvyAIR Meniscus System device is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Comparison to Predicate Device(s):

The IvyAIR Meniscus System has a similar intended use and similar technological characteristics to the predicate device: Smith & Nephew FAST-FIX 360 Meniscal Repair System. Any differences identified do not raise new questions of safety or effectiveness, as supported by biomechanical, biocompatibility and bench testing.

Technological Characteristics/Performance Data:

The IvyAIR Meniscus System 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 IvyAIR Meniscus System remains substantially equivalent to the predicate device. The device has been tested for biocompatibility according to ISO10993-1 and was determined to be biocompatible. Testing performed on the IvyAIR Meniscus System included the following:

Bench Testing	Biocompatibility Testing
Implant strength test to failure Dynamic and static tensile loading	MEM Elution Using L-929 Mouse Fibroblast Cells Guinea Pig Maximization Sensitization Test Intracutaneous Reactivity Test Acute Systemic Injection Test Material mediated pyrogen Subacute (14 Day) Intraperitoneal Toxicity Study In Rats Subchronic (14 Day) Intravenous Toxicity Study In Rats including histopathology Bacterial Mutagenicity Test (Ames Assay) In Vitro Mouse Lymphoma Assay In Vivo Mouse Micronucleus Assay Intramuscular Implantation Tests (2 weeks and 13 weeks)

All of the pre-determined acceptance criteria were met with passing results.

Clinical Testing:

Clinical evaluation is not required for this device.

Substantial equivalence:

The IvyAIR Meniscus System has the following similarities to the Smith & Nephew FAST-FIX 360 Meniscal Repair System predicate device cleared under K121861.

- 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 IvyAIR Meniscus System subject to this submission is as safe and effective as the Smith & Nephew FAST-FIX 360 Meniscal Repair System. It has the same indication for use, the same technological characteristics, and the same principles of operation as the Smith & Nephew FAST-FIX 360 Meniscal Repair System. The differences between the IvyAIR Meniscus System and the Smith & Nephew FAST-FIX 360 Meniscal Repair System raise no new issues of safety or effectiveness. Performance data demonstrate that the IvyAIR Meniscus System is as safe and effective as the Smith & Nephew FAST-FIX 360 Meniscal Repair System and is therefore substantially equivalent to the predicate device.