Mortise Medical LLC
Robert Hoy
Director of Research
124 South 600 West
Suite 100
Logan, Utah 84321

November 8, 2017

Re: K172620
Trade/Device Name: SyndesMetrics Syndesmosis Repair System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: August 31, 2017
Received: August 31, 2017

Dear Robert Hoy:

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 (DICE) 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 (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172620

Device Name

SyndesMetrics Syndesmosis Repair System

Indications for Use *(Describe)*

The SyndesMetrics Syndesmosis Repair System is intended for repair in the ankle including indications for:

Ankle syndesmosis fixation (syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures.

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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"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."

5. 510(k) Summary

Device Trade Name: SyndesMetrics Syndesmosis Repair System

Manufacturer:
Mortise Medical LLC
124 South 600 West, Suite 100
Logan, UT 84321

Contact:
Mr. Robert Hoy
Director of Research
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Date Prepared: October 26, 2017

Common Name: Single/multiple component metallic bone fixation appliances and accessories

Classification: 21 CFR 888.3030

Class: II

Product Code: HTN

Indications for Use:
The SyndesMetrics Syndesmosis Repair System is intended for repair in the ankle including indications for:

Ankle syndesmosis fixation (syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures.

Device Description:
The SyndesMetrics Syndesmosis Repair System consists of a Fibular Anchor and a Tibial Anchor which are connected by a length of suture. The implant is marketed with previously cleared ultra-high molecular weight polyethylene (UHMWPE) 3.5mm OrthoTape® (K150438) which is provided sterile packaged from Teleflex, Inc.

Predicate Devices:
The Arthrex, Inc. TightRope Syndesmosis Device (K043248) serves as the primary predicate device, and the JuggerLoc Bone to Bone System (K141219) serves as a reference predicate device.

Technological Characteristics Comparison:
The SyndesMetrics Syndesmosis Repair System and the predicates are similar in design, function, material, size and performance. Each subject and predicate device is designed to repair syndesmosis disruptions. Further, the subject device and TightRope Syndesmosis Device predicate device both consist of two cortical bone anchors and a length of suture material there between. The SyndesMetrics Syndesmosis Repair System subject device implants and the TightRope Syndesmosis Device predicate device implants are manufactured from titanium alloy and stainless steel materials with well-established biocompatibility and a long history of use in many previously cleared permanent implants. In addition, the subject and primary predicate device are for use with UHMWPE suture material.

Side-by-side mechanical performance testing demonstrates that the design differences between the SyndesMetrics Syndesmosis Repair System subject devices and the TightRope Syndesmosis Device predicate device raise no new safety and effectiveness questions.

Nonclinical Testing:
All necessary testing has been performed for the worst-case SyndesMetrics Syndesmosis Repair System to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of finished devices. The performance of the SyndesMetrics Syndesmosis Repair System was characterized through the following tests:

- Insertion Testing
- Pullout Strength Testing
- Fatigue Testing

Clinical data were not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence:
The Mortise Medical LLC SyndesMetrics Syndesmosis Repair System is substantially equivalent to the Arthrex, Inc. TightRope Syndesmosis Device (K043248) and the JuggerLoc Bone to Bone System (K141219) with respect to its indications for use, design, material, size, performance and function.