DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 19, 2017

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

Re: K171964
Trade/Device Name: LigaMetrics Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 29, 2017
Received: June 30, 2017

Dear Mr. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171964

Device Name
LigaMetrics Suture Anchors

Indications for Use *(Describe)*
The LigaMetrics Suture Anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Rotator cuff repair, Bankart repair, Slap lesion repair, Biceps tenodesis, Acromio-Clavicular separation, Deltoid repair, and Capsular shift or Capsulolabral reconstruction.

Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, Hallux valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair.

Knee: Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Iliotibial band tenodesis.

Hand/Wrist: Scapholunate ligament reconstruction, Ulnar collateral ligament reconstruction, Radial collateral ligament reconstruction.

Elbow: Biceps Tendon reattachment, Ulnar or radial collateral ligament reconstruction.

Hip: Distal row abductor tendon repair

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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510(k) Summary

Device Trade Name: LigaMetrics Suture Anchors

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

Contact: Mr. Robert Hoy
Director of Research
Phone: (614) 448-6358
Fax: (435) 213-4878
bob@surgicalfrontiers.com

Date Prepared: June 29, 2017

Common Name: Smooth or threaded metallic bone fixation fastener

Classification: 21 CFR 888.3040

Class: II

Product Code: MBI

Indications for Use:
The LigaMetrics Suture Anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

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Knee: Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Iliotibial band tenodesis.

Hand/Wrist: Scapholunate ligament reconstruction, Ulnar collateral ligament reconstruction, Radial collateral ligament reconstruction.

Elbow: Biceps Tendon reattachment, Ulnar or radial collateral ligament reconstruction.

Hip: Distal row abductor tendon repair.

Device Description:
The LigaMetrics Suture Anchors are offered in Threaded and Push-In versions and are designed to secure soft tissue to bone. The implant is marketed with previously cleared ultra-high molecular weight polyethylene (UHMWPE) 2.0mm OrthoTape® (K150438) which is provided sterile packaged from Teleflex, Inc.

Predicate Devices:
The Smith & Nephew, Inc. Footprint Ultra PK Suture Anchor (K093897, K113274, K123579) serves as the primary predicate, and the MTP Solutions LLC Titanium Suture Anchor (K133229) serves as a reference predicate device.

Technological Characteristics Comparison:
The LigaMetrics Suture Anchors and the predicates are similar in design, function, material, size and performance. Each subject and predicate device is designed to reattach soft tissue to bone. Further, the subject devices and Footprint Ultra PK Suture Anchor predicate device are designed to allow for anchor placement and independent suture tensioning and locking. The LigaMetrics Suture Anchor subject device implants and the Titanium Suture Anchor predicate device implants are manufactured from Ti-6Al-4V ELI (ASTM F136), a material with well-established biocompatibility and a long history of use in many previously cleared permanent implants. In addition, the subject and both predicate devices are for use with UHMWPE suture material.

Side-by-side mechanical performance testing demonstrates that the design differences between the LigaMetrics Suture Anchor subject devices and the Footprint Ultra PK Suture Anchor predicate device introduce no new issues of safety or effectiveness.

Nonclinical Testing:
All necessary testing has been performed for the worst-case LigaMetrics Suture Anchors 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 LigaMetrics Suture Anchors was characterized through the following tests:

- Insertion Testing
- Pullout Strength Testing
- Static Interconnection 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 LigaMetrics Suture Anchors are substantially equivalent to Smith & Nephew, Inc. Footprint Ultra PK Suture Anchor (K093897, K113274, K123579) and the MTP Solutions LLC Titanium Suture Anchor (K133229) with respect to their indications for use, design, material, size, performance and function.