August 1, 2023

Riverpoint Medical, LLC
Bianca Silva de Sousa
Regulatory Affairs Associate
815 NE 25th Ave
Portland, Oregon 97232

Re: K231278
Trade/Device Name: Iconix Knotless Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 2, 2023
Received: May 3, 2023

Dear Bianca De Sousa:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Jesse Muir -S

Jesse Muir, Ph.D.
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)*
K231278

Device Name
Iconix® Knotless Anchor

Indications for Use *(Describe)*
Iconix® Knotless Anchors are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific indications are listed below.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Repair

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Medial Patellofemoral Ligament (MPFL) Repair/ Reconstruction, Quadriceps Tendon Repair

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair, Proximal Hamstring 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.

RP RIVERPOINT

510(k) SUMMARY K231278

Iconix® Knotless Anchor

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Bianca Silva de Sousa (503) 517-8001
Date of Preparation:	May 1, 2023

Device Name

Trade Name:	Iconix® Knotless Anchor
Common or Usual Names:	Smooth or threaded metallic bone fixation fastener.
Classification Name:	21 CFR 888.3040: Smooth or Threaded Metallic Bone Fixation Fastener

Device Classification

FDA Class:	II
Product Classification:	888.3040: Smooth or Threaded Metallic Bone Fixation Fastener
Classification Code:	MBI
Review Panel:	Orthopedic
Premarket Review	Center for Device and Radiological Health Office of Health Technology (OHT6: Orthopedic Devices) Division of Health Technology 6C Restorative, Repair and Trauma Devices

Predicate Device

K151201 – Stryker ICONIX Anchors

No reference devices were used in this submission.

Device Description

The Iconix® Knotless Anchors are soft-tissue fixation devices, provided preloaded on a disposable inserter. The device is composed of a braided polyester anchor body that contains one working suture, also referred to as the repair strand, and a shuttle strand that is used to shuttle the repair strand around tissue and through the braided anchor body.

Sutures supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. Suture dyes are FDA approved. The inserter is comprised of metallic shaft with over molded handle. The device is sterilized by ethylene oxide gas and is provided sterile for single use. The anchor size will be available in 1.4mm with working sutures in standard USP size 2. Iconix® Knotless Anchor will be sold sterile for single use with no components or accessories. The device is intended for use in a hospital/clinic/surgical setting.

The classification for the Iconix® Knotless Anchor is FDA Class II device with product classification 21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener, Product Code MBI.

Intended Use and Indications for Use

Iconix® Knotless Anchors are intended to be used for soft-tissue to bone fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific indications are listed below.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair

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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Medial Patellofemoral Ligament (MPFL) Repair/ Reconstruction, Quadriceps Tendon Repair

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair, Proximal Hamstring Repair

Performance Data

The sutures used to construct the Iconix® Knotless Anchor meet requirements established by the United States Pharmacopeia (USP), except for diameter. The UHMWPE and Polyester sutures are tested per USP performance requirements for tensile strength.

FDA Guidance "Bone Anchors - Premarket Notification (510(k)) Submissions Guidance for Industry and Food and Drug Administration Staff" and FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" were followed during the preparation of this submission.

Non-clinical performance testing for the Iconix® Knotless Anchor included a sterilization adoption validation, biocompatibility testing per ISO10993- 1:2018 - *Biological Evaluation of Medical Devices*, stability testing on the product packaging per ISO 11607-1:2006 - *Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems*, usability engineering validation with simulated use in a cadaveric models performed per EN62366: 2015- *Medical devices - Application of usability engineering to medical devices.*

Non-clinical mechanical testing was performed to verify the fixation strength of the Iconix® Knotless Anchor using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the Iconix® Knotless Anchor device concluded that the device performed comparably to the predicate device in insertion, cyclic and pullout testing and the validations performed demonstrated that the Iconix® Knotless Anchor met all requirements for its intended use.

Substantial Equivalence and Comparison of Technical Characteristics

The Iconix® Knotless Anchor is substantially equivalent to the previously cleared Stryker ICONIX Anchor cleared per K151201 "predicate device." The Iconix® Knotless Anchor has the same intended use, similar principles of operation, and similar technological characteristics as the predicate device. Both the Iconix® Knotless Anchor and the predicate device are comprised of the same materials, packaged using the same packaging materials and sterilized using the same processes. The Iconix® Knotless Anchor subject device contains slight technological differences from the predicate device in the following ways: i) indications for use; ii) principles of operation. These technical characteristics are within the range of currently marketed devices, and they have been assessed through risk analysis, not raising any new questions of safety of effectiveness.
Therefore, the Iconix® Knotless Anchor "subject device" is substantially equivalent to the predicate device in both technological characteristics and intended use and does not raise any issues of safety or effectiveness.

Conclusion

The information provided in this Traditional 510(k) demonstrates that the Iconix® Knotless Anchor is substantially equivalent to the predicate device.