



July 3, 2024

Riverpoint Medical
Bianca Silva de Sousa
Regulatory Associate II
825 NE 25th Ave
Portland, Oregon 97232

Re: K241577

Trade/Device Name: Iconix® 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 31, 2024
Received: June 3, 2024

Dear Mrs. Silva 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert M. Stefani -S

2024.07.03 09:14:23 -04'00'

For: 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

Indications for Use

Submission Number (if known)

K241577

Device Name

Iconix® Anchor

Indications for Use (Describe)

The Iconix® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY**Iconix® 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: July 2, 2024

Device Name

Trade Name: Iconix® Anchor

Common or Usual Names: Fastener, Fixation, Nondegradable, Soft Tissue

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

K231078 – All-Suture Anchor

Reference Devices

K233468 - Iconix Anchor

K240213 - Iconix Knotless Anchor

Device Description

The Iconix[®] Anchors are soft-tissue to bone fixation devices, provided preloaded on a disposable inserter. The device is composed of a braided polyester anchor body that contains one or more working sutures. Sutures supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. Suture dyes are FDA approved (K100006 and K190817). The standard and the self-punching inserters are comprised of metallic shaft with over molded handle. The device is sterilized by ethylene oxide gas and is provided sterile for single use. The Iconix[®] Anchors size is 2.3mm. The anchors will be sold sterile for single use with no components or accessories. The product is intended to be used with the same accessories used to implant the predicate device. The device is intended for use in a hospital/clinic/surgical setting, and it is intended for adults only.

The classification for the Iconix[®] 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

The Iconix[®] 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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Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair, Proximal Hamstring Repair

Performance Data

The sutures used to construct the Iconix[®] Anchor meet requirements established by the United

States Pharmacopeia (USP), except for diameter. The UHMWPE 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[®] Anchor included shelf-life testing, 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[®] Anchor using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the Iconix[®] 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[®] Anchor met all requirements for its intended use.

Substantial Equivalence and Comparison of Technical Characteristics

The Iconix[®] Anchor is substantially equivalent to the previously cleared All-Suture Anchor per K231078 “predicate device.” The Iconix[®] Anchor has the same intended use, same principles of operation, and similar technological characteristics as the predicate device. Both the Iconix[®] Anchor and the predicate device have the same anchor geometry and method of fixation of suture to anchor. They’re also packaged using the same packaging materials and sterilized using the same processes. The only difference between Iconix[®] Anchor subject device and the predicate device is in technological characteristics, specifically in (i) range of suture size – the subject device contains sutures size 1.2mm and 2.2mm, while the predicate device has 1.2mm, 1.8mm and #2, (ii) anchor materials – the anchor of the subject device does not contain a coating. However, the technological characteristics are within the range of currently marketed devices, as seen in the reference devices Iconix Knotless Anchor (K240213) and Iconix Anchors (K233468), and they have been assessed through risk analysis, not raising any new questions of safety or effectiveness. Therefore, the Iconix[®] Anchor “subject device” is substantially equivalent to the “predicate device” and does not raise any new issues of safety or effectiveness.

Conclusion

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