July 30, 2025

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

Re: K252144
Trade/Device Name: Iconix Speed Anchor; Iconix Speed HA+ Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 7, 2025
Received: July 8, 2025

Dear Bianca 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252144

Please provide the device trade name(s).

Iconix Speed Anchor;
Iconix Speed HA+ Anchor

Please provide your Indications for Use below.

Iconix Speed Anchors are intended to be used for soft-tissue to bone fixation in the shoulder. They are indicated for use in rotator cuff repair.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY
Iconix Speed Anchor
Iconix Speed HA+ 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 7, 2025

Device Name

Trade Name:	Iconix Speed Anchor and Iconix Speed HA+ 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

K233468 – Iconix Anchor

No reference devices were used in this submission.

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Device Description

The Iconix Speed Anchors are soft-tissue to bone fixation devices, provided preloaded on a disposable self-punching inserter. The device is composed of a braided polyester anchor body that contains two or three working sutures. The anchor is inserted into the bone using a self-punching mechanism, and the polyester sheath bunches as the anchor is deployed to allow for fixation in bone.

Sutures supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. Suture dyes are FDA approved. The 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. Iconix Speed Anchors are available in common sizes and lengths and will be sold sterile for single use. The device is intended for use in a hospital/clinic/surgical setting.

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

Iconix Speed Anchors are intended to be used for soft-tissue to bone fixation in the shoulder. They are indicated for use in rotator cuff repair.

Performance Data

The sutures used to construct the Iconix Speed 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 Speed 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 Speed Anchor using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the Iconix Speed 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 Speed Anchor met all requirements for its intended use.

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Substantial Equivalence and Comparison of Technical Characteristics

The Iconix Speed Anchor is substantially equivalent to the previously cleared Iconix Anchor per K233468 “predicate device.” The Iconix Speed Anchor has similar technological characteristics, and same intended use and principles of operation as the predicate device. Both the Iconix Speed Anchor and the predicate device are sterilized using the same processes. The only difference between Iconix Speed Anchor subject device and the predicate device is in technological characteristics, specifically the inserter design, packaging configuration, and anchor coating. However, the technological 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 Speed Anchor “subject device” is substantially equivalent to the “predicate device” and does not raise any issues of safety or effectiveness.

Conclusion

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