October 29, 2024

Riverpoint Medical
Paul Vagts
Senior Regulatory Associate III
825 NE 25th Ave
Portland, Oregon 97232

Re: K243203
Trade/Device Name: OC JuggerKnotless Soft Anchor; OC JuggerLoop Soft Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, MAI
Dated: September 30, 2024
Received: October 1, 2024

Dear Paul Vagts:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243203

Device Name

OC JuggerKnotless Soft Anchor;
OC JuggerLoop Soft Anchor

Indications for Use *(Describe)*

The OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor are intended for use in soft tissue to bone fixation in the following indications:
Knee MPFL
Knee Patellar tendon repair
Knee MCL
Knee Quadriceps tendon repair
Foot and Ankle Achilles tendon repair
Foot and Ankle Medial/lateral repair and reconstruction
Foot and Ankle Plantar plate repair
Foot and Ankle Mid- and forefoot repair
Foot and Ankle Metatarsal ligament/tendon repair or reconstruction
Shoulder Rotator Cuff
Shoulder Shoulder Instability
Shoulder Biceps Tenodesis
Elbow Lateral epicondylitis repair
Elbow Biceps tendon reattachment

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

RP RIVERPOINT

510(k) SUMMARY
Riverpoint Medical OC JuggerKnotless and OC JuggerLoop Soft Anchors
K243203

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:	Paul Vagts (503) 517-8001
Date of Preparation:	October 25th, 2024

Device Name

Trade Name:	OC JuggerKnotless Soft Anchor; OC JuggerLoop Soft Anchor
Common or Usual Names:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name:	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
Subsequent Code:	MAI

Predicate Device

K232411 – Riverpoint Medical JuggerKnot Soft Anchor with OC Coating

Device Description

The OC JuggerKnotless® Soft Anchor is comprised of a suture sleeve structure and working suture. Non-absorbable braided ultra-high molecular weight polyethylene (UHMWPE) sutures are spliced through a non-absorbable braided polyester suture anchor sleeve. Up to two non- absorbable round and flat braided UHMWPE working

RP RIVERPOINT

sutures can be added inside the suture anchor sleeve. The UHMWPE sutures are available undyed (white), blue, or black Available Suture sizes are standard according to USP requirements (dependent on suture type). The hydroxyapatite and bioceramic particles are embedded in the surface of the suture anchor material.

The OC JuggerLoop® Soft Anchor is comprised of a suture sleeve structure and shuttling and cinching suture. Non-absorbable braided ultra-high molecular weight polyethylene (UHMWPE) sutures are spliced through a non-absorbable braided polyester suture anchor sleeve. Up to two non-absorbable round and flat braided UHMWPE working sutures can be added inside the suture anchor sleeve. The UHMWPE sutures are available undyed (white), blue, or black. Available Suture sizes are standard according to USP requirements (dependent on suture type). The hydroxyapatite and bioceramic particles are embedded in the surface of the suture anchor material.

Suture supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. Suture dyes are FDA approved. The inserter is comprised of a metallic shaft with a standard or self-punching tip and an overmolded handle. The device is sterilized by ethylene oxide gas and is provided sterile for single use. OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor are available in common sizes and lengths and 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 OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor are FDA Class II device with product classification 21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener, Product Code MBI with subsequent product classification 21 CFR §888.3030: Single/multiple component metallic bone fixation appliances and accessories, Product Code MAI.

Intended Use / Indications for Use

OC JuggerKnotless Soft Anchors and OC JuggerLoop Soft Anchors are intended for use in soft tissue to bone fixation for the following indications:

Knee	MPFL
Knee	Patellar tendon repair
Knee	MCL
Knee	Quadriceps tendon repair
Foot and Ankle	Achilles tendon repair
Foot and Ankle	Medial/lateral repair and reconstruction
Foot and Ankle	Plantar plate repair
Foot and Ankle	Mid- and forefoot repair
Foot and Ankle	Metatarsal ligament/tendon repair or reconstruction
Shoulder	Rotator Cuff
Shoulder	Shoulder Instability
Shoulder	Biceps Tenodesis
Elbow	Lateral epicondylitis repair
Elbow	Biceps tendon reattachment

RP RIVERPOINT

Performance Data

The sutures used to construct the JuggerKnotless Soft Anchors and JuggerLoop Soft Anchors meet requirements established by the United States Pharmacopeia (USP), except for diameter. The UHMWPE sutures are tested per USP performance requirements for needle attachment and 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 JuggerKnotless Soft Anchor and JuggerLoop Soft Anchor included a usability engineering validation with simulated use in a cadaveric models performed per EN62366: 2015- Medical devices - Application of usability engineering to medical devices. Endotoxin/pyrogenicity testing was performed per ANSI/AAMI ST72:2019, USP <161>, USP <151> and USP <85>. Non-clinical mechanical testing was performed to verify the fixation strength of the OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor concluded that the device performed comparably to the predicate device and to other currently marketed soft anchor devices in insertion, cyclic and pullout testing, and the validations performed demonstrated that the OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor met all requirements for its intended use.

Substantial Equivalence and Comparison of Technical Characteristics

The OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor is substantially equivalent to the previously cleared JuggerKnot® Soft Anchor with OC coating cleared per K232411 “predicate device.” The OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor has the same intended use, similar principles of operation, and similar technological characteristics as the predicate device. Both the subject device and the predicate device are comprised of the same materials, packaged using the same packaging materials and sterilized using the same processes. The OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor subject devices contains slight technological differences from the JuggerKnot® with OC coating predicate device in the following way: the soft anchor assembly. However, these technical characteristics are within the range of currently marketed devices. Therefore, the OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft 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 Special 510(k) demonstrates that the Riverpoint Medical OC JuggerKnotless Soft Anchor and OC JuggerLoop Soft Anchor subject device is substantially equivalent to the predicate device.