



April 11, 2024

Riverpoint Medical
Becca Defrancia
Regulatory Affairs Manager
825 NE 25th Ave
Portland, Oregon 97232

Re: K240719

Trade/Device Name: OC JuggerKnot® 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: March 7, 2024
Received: March 15, 2024

Dear Becca Defrancia:

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,

Ryan Trombetta -S

Digitally signed by Ryan
Trombetta -S
Date: 2024.04.11 16:01:21 -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)

K240719

Device Name

OC JuggerKnot® Soft Anchor

Indications for Use (Describe)

OC JuggerKnot® Soft Anchor 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

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
Riverpoint Medical OC JuggerKnot® Soft Anchor

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25 th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or (971) 288-1083
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Becca DeFrancia (503) 517-8001
Date of Preparation:	March 8, 2024

Device Name

Trade Name:	OC JuggerKnot® 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
Primary Product Code:	MBI
Product Code:	MAI

Predicate Device

K232411 – Riverpoint Medical JuggerKnot® Soft Anchor with OC Coating

Reference Device

K231128 – Riverpoint Medical JuggerKnot® Soft Anchor

Device Description

The OC JuggerKnot® 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 three 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, black or with or without a stainless steel needle attached. 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 self-punching tip and an overmolded handle. The device is sterilized by ethylene oxide gas, and is provided sterile for single use. OC JuggerKnot® Soft Anchors are available in common sizes and lengths with or without pre-attached 302 stainless steel needles 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 JuggerKnot® Soft Anchor is 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 JuggerKnot® 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

Performance Data

The sutures used to construct the OC JuggerKnot® 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 OC JuggerKnot® Soft Anchor with self-punching inserter 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 JuggerKnot® Soft Anchor with self-punching inserter using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the OC JuggerKnot® Soft Anchor device with self-punching inserter concluded that the device performed comparably to the predicate device and to other currently marketed soft anchor devices with self-punching inserters in insertion, cyclic and pullout testing and the validations performed demonstrated that the OC JuggerKnot® Soft Anchor with self-punching inserter met all requirements for its intended use.

Substantial Equivalence and Comparison of Technical Characteristics

The OC JuggerKnot® Soft Anchor with self-punching inserter is substantially equivalent to the previously cleared JuggerKnot® Soft Anchor with OC coating cleared per K232411 “predicate device.” The OC JuggerKnot® Soft Anchor with self-punching inserter has the same intended use, similar principles of operation, and similar technological characteristics as the predicate device. Both the OC JuggerKnot® Soft Anchor with self-punching inserter and the predicate device are comprised of the same materials, packaged using the same packaging materials and sterilized using the same processes. The OC JuggerKnot® Soft Anchor subject device contains slight technological differences from the JuggerKnot® with OC coating predicate device in the following way: the self-punching inserter tip configuration. However, these technical characteristics are within the range of currently marketed devices such as reference device JuggerKnot® Soft Anchor with self-punching inserter. Therefore, the OC JuggerKnot® Soft Anchor “subject device” with self-punching inserter 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 JuggerKnot® Soft Anchor subject device with self-punching inserter is substantially equivalent to the predicate device.