October 6, 2023

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

Re: K232411
Trade/Device Name: JuggerKnot Soft Anchor OC
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 10, 2023
Received: August 10, 2023

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,

Sara S. Thompson -S

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

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)*
K232411

Device Name
JuggerKnot Soft Anchor OC

Indications for Use *(Describe)*
JuggerKnot Soft Anchor OC 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
Hip Acetabular labral repair
Hip Proximal hamstring repair
Hip Hip Labral reconstruction
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.

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510(k) SUMMARY

JuggerKnot Soft Anchor OC

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:	Becca DeFrancia (503) 517-8001
Date of Preparation:	August 9, 2023

Device Name

Trade Name:	JuggerKnot Soft Anchor OC
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 Devices

Legally Marketed Primary Predicate Device to Which Substantial Equivalence is Claimed:

- Riverpoint Medical JuggerKnot Soft Anchor (K203740)

Reference Devices:

- Wishbone Medical, Inc. Smart Correction System Rings and Compatible HA-Coated Half Pins (K221366)
- Smith and Nephew, Inc. Osteoraptor Suture Anchor (K082215)
- SIGNAFUSE Bioactive Bone Graft (K193513)

Device Description

The JuggerKnot Soft Anchor OC is identical to the previously cleared JuggerKnot Soft Anchor OC except for the presence of a bioceramics embedded in the anchor portion of the device. The JuggerKnot Soft Anchor OC is comprised of a suture sleeve structure and working suture. Non-absorbable braided ultra-high molecular weight polyethylene (UHMWPE) sutures are spliced through a suture anchor sleeve comprised of non-absorbable braided polyester. Up to two non-absorbable round or flat braided UHMWPE working sutures can be added inside the suture anchor sleeve. The UHMWPE sutures are available undyed (white) and black. The hydroxyapatite and bioceramic particles are embedded in the surface of the suture anchor material.

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 a metallic shaft with over molded handle. The device is sterilized by ethylene oxide gas and is provided sterile for single use. The JuggerKnot Soft Anchor OC 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 JuggerKnot Soft Anchor OC 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 and Indications for Use

JuggerKnot Soft Anchor OC 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
Hip	Acetabular labral repair
Hip	Proximal hamstring repair
Hip	Hip Labral reconstruction
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 JuggerKnot Soft Anchor OC 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, Food and Drug Administration Staff", FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA", and FDA Guidance "510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants" were followed during the preparation of this submission.

Non-clinical performance testing for the JuggerKnot Soft Anchor OC 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.* 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 JuggerKnot Soft Anchor OC using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the JuggerKnot Soft Anchor OC device concluded that the device performed comparably to the predicate device in insertion, cyclic and pullout testing and the validations performed demonstrated that the JuggerKnot Soft Anchor OC met all requirements for its intended use. An animal study was performed to evaluate the biological safety and in vivo performance associated with the JuggerKnot Soft Anchor OC. The animal study demonstrated substantially equivalent biological safety and in vivo performance to the predicate device of the JuggerKnot Soft Anchor OC.

The substantial equivalence of the JuggerKnot Soft Anchor OC is supported by the extensive non-clinical and animal testing presented in this 510(k).

Substantial Equivalence and Comparison of Technical Characteristics

The JuggerKnot Soft Anchor OC is substantially equivalent to the previously cleared JuggerKnot Soft Anchor Suture Anchor cleared per K203740 "predicate device." The JuggerKnot Soft Anchor OC has the same intended use, same principles of operation, and similar technological characteristics as the predicate device. The JuggerKnot Soft Anchor OC subject device contains slight technological differences from the predicate device but are within the range of currently marketed devices, and they have been assessed through risk analysis, not raising any new questions of safety or effectiveness.

Therefore, the JuggerKnot Soft Anchor OC "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 Traditional 510(k) demonstrates that the JuggerKnot Soft Anchor OC is substantially equivalent to the predicate device K203740.