February 12, 2021

Riverpoint Medical
Amanda Cole
Regulatory Affairs Associate
825 NE 25th Ave.
Portland, Oregon 97232

Re: K203740
Trade/Device Name: 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
Dated: December 21, 2020
Received: December 22, 2020

Dear Amanda Cole:

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 (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 located 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.

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

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

for

Laura C. Rose, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203740

Device Name
JuggerKnot® Soft Anchor

Indications for Use *(Describe)*

Indicated 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.

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510(k) SUMMARY

JuggerKnot® Soft Anchor

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Amanda Cole (503) 517-8001
Date of Preparation:	December 21, 2020

Device Name

Trade Name:	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
Classification Code:	MBI
Review Panel	Orthopedic
Premarket Review	Office of Device Evaluation Division of Orthopedic Devices, Restorative and Repair Devices Branch (RRDB)

Predicate Device

K150768 – Zimmer Biomet JuggerKnot® Soft Anchor

No reference devices were used in this submission.

Device Description

The 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).

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 metallic shaft with overmolded handle. The device is sterilized by ethylene oxide gas, and is provided sterile for single use. 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 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.

Intended Use and Indications for Use

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
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 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 JuggerKnot® Soft Anchor 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 the JuggerKnot® Soft Anchor using insertion, cyclic and pullout testing as compared to the predicate device. Results of performance testing for the JuggerKnot® Soft Anchor device 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 JuggerKnot® Soft Anchor met all requirements for its intended use.

Substantial Equivalence and Comparison of Technical Characteristics

The JuggerKnot® Soft Anchor is substantially equivalent to the previously cleared JuggerKnot® Soft Anchor cleared per K150768 "predicate device." The JuggerKnot® Soft Anchor has the same intended use, the same principles of operation, and similar technological characteristics as the predicate device. Both the JuggerKnot® Soft Anchor and the predicate device are comprised of the same materials, packaged using the same packaging materials and sterilized using the same processes. The JuggerKnot® Soft Anchor subject device contains slight technological differences from the JuggerKnot® predicate device in the following ways: i) the flat braid configuration of UHMWPE sutures ii) triple loaded anchor configuration (up to three sutures spliced into the anchor) and iii) fixed (non-sliding) positioning of the suture anchor. The JuggerKnot® Soft Anchor predicate device anchor is a sliding anchor with up to two round braid UHMWPE working sutures spliced in the anchor. However, these technical characteristics is within the range of currently marketed devices. Therefore, the JuggerKnot® Soft Anchor "subject device" is substantially equivalent to the predicate devices in both technological characteristics and intended use 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 substantially equivalent to the predicate device.