October 23, 2023

Responsive Arthroscopy LLC
Garrett Ahlborg
Director of Regulatory, Quality and Compliance
701 N 3rd Street, Suite 208
Minneapolis, Minnesota 55401

Re: K233258
Trade/Device Name: Shadow Knotless All-Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 28, 2023
Received: September 28, 2023

Dear Garrett Ahlborg:

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)*
K233258

Device Name
Shadow Knotless All-Suture Anchors

Indications for Use *(Describe)*
The Shadow Knotless All-Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Repairs.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair.

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.

510(k) SUMMARY

DATE PREPARED: October 19, 2023

SUBMITTER INFORMATION:
Responsive Arthroscopy LLC
701 N. 3rd Street, Suite 208
Minneapolis, MN 55401

ESTABLISHMENT REGISTRATION: 3015200759

CONTACT INFORMATION:
Garrett Ahlborg
Director of Regulatory, Quality and Compliance
(612) 532-6800
Gahlborg@responsivesports.com

DEVICE INFORMATION:

Trade Name:	Shadow Knotless All-Suture Anchors
Common Name:	Suture Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Product Code:	MBI
Classification:	Class II
Regulation Number:	21 CFR 888.3040
Predicate Device:	Responsive Arthroscopy Mini Stealth All-Suture Anchors (K230094)
Additional Predicate Devices:	Responsive Arthroscopy Wedge Push-In Suture Anchors (K190446, K181076)

The predicate devices have not been subject to any design-related recalls.

DEVICE DESCRIPTION:

The Shadow Knotless All-Suture Anchor is a modified version of the Responsive Arthroscopy (RA) Mini Stealth All-Suture Anchors that were previously cleared under K230094. The subject Shadow Knotless device is a suture anchor intended for the fixation of soft tissue to bone. The Shadow device features a knotless, push-in design and is comprised entirely of suture material configured to provide an anchor in bone. The anchor creates a secure fixation point for the reattachment of soft tissue to bone when it is inserted through a pilot hole and deployed against the inserter tip below cortical bone in the desired anatomy. The subject device features four longitudinally arranged round bundles that bunch together and expand radially when deployed to achieve fixation. The provided suture passing loop allows the integrated repair suture to be passed through the anchor body when securing the desired soft tissue, while the knotless feature allows the repair suture to be locked in place without tying a knot. The anchors may be delivered arthroscopically using inserters and reusable surgical instruments such as drills, guide tubes, and probes, which are identical to those provided with the predicate Mini Stealth All-Suture Anchors (K230094). The subject Shadow anchors are pre-loaded on disposable inserters and provided sterile via ethylene oxide (EO), while the reusable instruments are non-sterile and are intended to be sterilized by the end user.

The subject Shadow device is designed for a 2.1mm diameter pilot hole and is comprised of braided nonabsorbable ultra-high molecular weight polyethylene (UHMWPE). It is provided with an attached USP #1 UHMWPE nonabsorbable repair suture tail and a UHMWPE suture passing loop that are used to facilitate a repair. All subject device materials are identical to those of the predicate Mini Stealth All-Suture Anchors (K230094).

The primary differences between the subject and predicate devices (K230094) are the additions of the knotless feature, integrated repair suture tail, and suture passing loop. However, these design characteristics are similar to those found in the predicate RA Wedge Push-In Suture Anchors previously cleared under K190446 and K181076. No other changes are being made to the inserters or other instrumentation that may be used during a procedure.

INDICATIONS FOR USE:

The Shadow Knotless All-Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair, Digital Tendon Transfers.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Carpal Ligament Reconstruction, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP Joints for all Digits, Digital Tendon Repairs.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair.

TECHNOLOGICAL CHARACTERISTICS:

The subject Shadow Knotless All-Suture Anchors have the same intended use, indications for use, and fundamental scientific technology as the predicate Mini Stealth All-Suture Anchors cleared under K230094. Both the subject device and the predicate device feature similar technological characteristics, including a soft anchor design, principles of operation and insertion method, and identical materials, packaging, shelf life, and sterilization method. In addition, both the subject devices and predicate devices are provided sterile, single use only, and pre-loaded on the same inserter.

The subject device features slight differences in technology as compared to the primary predicate device (K230094), including a knotless design, integrated repair suture tail, and a suture passing loop. However, these technological characteristics are similar to those found in the additional predicate RA Wedge Push-In Suture Anchors (K190446 and K181076). Therefore, these technological characteristics are deemed equivalent to the predicate devices and have no impact on the ability of the subject devices to fulfill their intended use.

SUBSTANTIAL EQUIVALENCE:

The subject Shadow Knotless All-Suture Anchors have the same intended use, indications for use, and fundamental scientific technology as the predicate devices. The design modifications do not raise different questions of safety or efficacy. Therefore, the Shadow Knotless All-Suture Anchors are substantially equivalent to the predicate devices.

PERFORMANCE TESTING:

Nonclinical performance testing was completed to demonstrate that the subject Shadow Knotless All-Suture Anchors met the established performance characteristics and design requirements. Performance testing consisted of design verification testing (bench testing). All testing met acceptance criteria and demonstrated that the devices met design specifications and performed as intended.

The following bench testing was performed on the subject devices:

- Insertion Force Testing
- Cyclic Pullout Force Testing
- Cyclic Suture Locking Force Testing
- Suture Diameter Measurement
- Suture Tensile Strength Testing

In summary, performance testing of the Shadow Knotless All-Suture Anchors indicated no new risks and demonstrated substantial equivalence in performance compared to the legally marketed predicate devices.

CONCLUSION:

In conclusion, the subject devices have the same indications for use, intended use, and similar technological characteristics as the predicate devices. The design modifications raise no new or different issues of safety and effectiveness, and performance testing has demonstrated that the subject device is at least as safe and effective as the predicate devices. Therefore, the subject device is substantially equivalent to the predicate devices.