August 25, 2023

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

Re: K230094
Trade/Device Name: Responsive Arthroscopy Stealth and Mini Stealth 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: August 1, 2023
Received: August 1, 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 (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,

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)*
K230094

Device Name
Responsive Arthroscopy Stealth and Mini Stealth All-Suture Anchors

Indications for Use *(Describe)*
The Responsive Arthroscopy Stealth and Mini Stealth 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 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.

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510(k) SUMMARY

DATE PREPARED: August 2, 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:	Responsive Arthroscopy Stealth and Mini Stealth 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
Primary Predicate Device:	Stryker ICONIX All-Suture Anchor System (K133671)
Additional Predicate Device:	Stryker ICONIX TT All-Suture Anchor System (K170098)
Reference Devices:	HS Fiber (Polyblend) (K100006) HS SutureTape (K153307)

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

DEVICE DESCRIPTION:

The Stealth and Mini Stealth All-Suture Anchors are soft anchors intended for the fixation of soft tissue to bone. The All-Suture Anchors feature a push-in design and are comprised entirely of suture material configured to provide an anchor in bone. The anchors create a secure fixation point for the reattachment of soft tissue to bone when they are inserted through a pilot hole and deployed against the inserter tip below cortical bone in the desired anatomy. The All-Suture Anchors feature four longitudinally arranged round bundles that bunch together and expand radially when deployed to achieve fixation. The All-Suture Anchors may be delivered arthroscopically using inserters and surgical instruments such as drills, guide tubes, and probes.

The subject device systems include two anchor sizes, the Stealth All-Suture Anchor which is designed for a 3.0mm diameter pilot hole and the Mini Stealth All-Suture Anchor which is designed for a 2.1mm diameter pilot hole. Both anchor systems are comprised of braided nonabsorbable ultra-high molecular weight polyethylene (UHMWPE) material and are available in a variety of configurations containing one or more working USP #2 sutures or 1.5mm suture tapes to facilitate a repair.

The Stealth and Mini Stealth All-Suture 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.

INDICATIONS FOR USE:

The Responsive Arthroscopy Stealth and Mini Stealth 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 Repair.

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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 Repair.

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

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

TECHNOLOGICAL CHARACTERISTICS:

The subject Stealth and Mini Stealth All-Suture Anchors have the same intended use, indications for use, and fundamental scientific technology as the predicate devices cleared under K133671. Both the subject devices and the predicate devices feature similar technological characteristics, including a soft anchor design, principles of operation and insertion method, materials, repair suture offerings, packaging and shelf life, and sterilization method. In addition, both the subject devices and predicate devices are provided sterile and single use only pre-loaded on an inserter.

The subject devices feature slight differences in technology as compared to the predicate devices, including implant construct design, pre-deployment and post-deployment anchor dimensions, pilot hole dimensions, and implant deployment method. However, 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 Stealth and Mini Stealth All-Suture Anchors have the same intended use, indications for use and fundamental scientific technology as the predicate devices, while having similar technological characteristics. The differences in technology do not raise different questions of safety or efficacy. Therefore, the Stealth and Mini Stealth All-Suture Anchors are substantially equivalent to the predicate devices.

PERFORMANCE TESTING:

Nonclinical performance testing was completed to demonstrate that the Stealth and Mini Stealth All-Suture Anchors met the established performance characteristics and design requirements. Performance testing consisted of design verification testing (bench testing) that included side-by-side comparative testing with the predicate devices, shelf-life validation, extractable residue testing, and cytotoxicity testing. All testing met acceptance criteria and demonstrated that the devices met design specifications and performed as intended.

The following testing was performed on the subject devices**:**

- Insertion Force Testing
- Cyclic Pullout Force Testing
- Shelf-life Testing per ASTM F1980
- Extractable Residue Testing per ASTM F2459
- MEM Elution Testing per ISO 10993-5

In summary, performance testing of the Stealth and Mini Stealth 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 fundamental scientific technology as the predicate devices. The differences in technological characteristics raise no new or different issues of safety and effectiveness, and performance testing has demonstrated that the subject devices are at least as safe and effective as the predicate devices. Therefore, the subject devices are substantially equivalent to the predicate devices.