October 13, 2022

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

Re: K222763
Trade/Device Name: Responsive Arthroscopy Mustang and Mustang Knotless 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 12, 2022
Received: September 13, 2022

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222763

Device Name

Responsive Arthroscopy Mustang and Mustang Knotless Suture Anchors

Indications for Use *(Describe)*

The Responsive Arthroscopy Mustang and Mustang Knotless Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, hand/wrist, and elbow in the following procedures:

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

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

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis 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: October 12, 2022

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 Mustang and Mustang Knotless 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 Suture Anchor System (K180951)
Reference Devices:	HS Fiber (Polyblend) (K100006) HS SutureTape (K153307)

DEVICE DESCRIPTION:

The Mustang and Mustang Knotless Suture Anchors are modified versions of the RA Large Screw-in Suture Anchors and the Large Push-In Suture Anchors, respectively, that were previously cleared under K180951. The Mustang and Mustang Knotless Suture Anchors are families of suture anchors intended for the fixation of soft tissue to bone. Both Mustang systems include two diameter sizes of suture anchors made of polyether ether ketone (PEEK) per ASTM F2026 along with repair suture or suture tape, inserters, awls, and taps.

Both the Mustang and Mustang Knotless device families include several configurations that differ in anchor diameter and suture offerings to accommodate various procedures and patient anatomies.

The Mustang Suture Anchors will be offered in two diameter sizes (4.5 and 5.5mm) and are provided with either two #2 sutures or one 1.5 mm suture tape (4.5mm anchor); or three #2 sutures or two 1.5mm suture tapes (5.5mm anchor).

The Mustang Knotless Suture Anchors will be offered in two diameter sizes (4.75 and 5.5mm) and are designed to accept up to six #2 suture tails or two 1.5mm suture tape tails (4.75mm anchor); or up to

eight #2 suture tails or four 1.5mm suture tape tails (5.5mm anchor). The Mustang Knotless Suture Anchors also feature a suture pull tab and an auxiliary #0 suture that holds the anchor in place until use.

The Mustang and Mustang Knotless Suture Anchors are pre-loaded on disposable inserters and provided sterile via ethylene oxide (EO).

The only differences between the subject devices and the predicate devices are considered minor and include modified anchor body geometry, modified anchor body dimensions, increase in the number of sutures or suture tapes compatible with the implants, modified internal locking screw geometry and dimensions, and the addition of vent holes to the anchor bodies. In addition, the subject Mustang Knotless Suture Anchor inserter has been modified slightly to correspond with the anchor changes. No other changes are being made to the inserters or other instrumentation that may be used during a procedure.

MATERIALS:

The Mustang and Mustang Knotless Suture Anchors feature the same materials as the predicate devices. The anchors are machined from extruded PEEK per ASTM F2026. Implantable repair sutures are either Riverpoint Medical #2 HS Fiber ultra-high molecular weight polyethylene suture previously cleared under K100006 or Riverpoint Medical ultra-high molecular weight polyethylene HS SutureTape previously cleared under K153307.

INDICATIONS FOR USE:

The Responsive Arthroscopy Mustang and Mustang Knotless Suture Anchors are intended to be used for fixation of soft tissue to bone in the shoulder, foot/ankle, hand/wrist, and elbow in the following procedures:

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

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

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair

TECHNOLOGICAL CHARACTERISTICS:

The Mustang and Mustang Knotless Anchors (subject devices) have the same indications for use and fundamental scientific technology as the predicate Responsive Arthroscopy Suture Anchor System (K180951).

The subject devices have the same technological characteristics (i.e., principles of operation, basic design, manufacturing process, functionality, materials, biocompatibility, shelf life and sterile packaging) as the predicate devices. The subject devices feature modified anchor body geometry, modified anchor body dimensions, increase in the number of sutures or suture tapes compatible with the implants, modified internal locking screw geometry and dimensions, and the addition of vent holes to the anchor bodies.

SUBSTANTIAL EQUIVALENCE:

The subject Mustang and Mustang Knotless Suture Anchors have the same 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 Mustang and Mustang Knotless Suture Anchors are substantially equivalent to the predicate devices.

PERFORMANCE TESTING:

Nonclinical performance testing was completed to demonstrate that the Mustang and Mustang Knotless 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
- Insertion Torque Testing
- Cyclic Pullout Force Testing
- Suture Locking Force Testing

In summary, performance testing of the Mustang and Mustang Knotless 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 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 devices are at least as safe and effective as the predicate devices. Therefore, the subject devices are substantially equivalent to the predicate devices.