January 30, 2025

Responsive Arthroscopy, Inc.
Gretchen Hinchley
VP of Quality, Regulatory, and Compliance
701 N. 3rd Street
Suite 208
Minneapolis, Minnesota 55401

Re: K243726
Trade/Device Name: Osprey Suture 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 3, 2024
Received: December 3, 2024

Dear Gretchen Hinchley:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243726

Device Name

Osprey Suture Anchor

Indications for Use *(Describe)*

The Osprey Suture Anchor is intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, and elbow in the following procedures:

- Shoulder: Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair.

- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.

- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Meniscal Root Repair. Secondary fixation for ACL/PCL 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.

510(k) SUMMARY

DATE PREPARED: January 30, 2025

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

ESTABLISHMENT REGISTRATION: 3015200759

CONTACT INFORMATION:
Gretchen Hinchley
VP of Quality, Regulatory and Compliance
(612) 867-6795
Ghinchley@responsivesports.com

DEVICE INFORMATION:

Trade Name:	Osprey Suture Anchor
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:	Arthrex Swivelock Suture Anchor (K173845)
Additional Predicate Device:	Responsive Arthroscopy Valor Push-In Suture Anchors (K180951)

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

DEVICE DESCRIPTION:

The Osprey Suture Anchor is an anchor device comprised of polyether ether ketone (PEEK) material that is designed for the fixation of soft tissue to bone. The device creates a secure point for the fixation of soft tissue to bone when inserted through a pilot hole and deployed within bone. The system features a knotless 5.35mm diameter suture anchor preloaded on an inserter with two suture pull tabs. The system also includes two 2.3mm repair suture tapes and an auxiliary #0 suture that holds the anchor in place on the inserter until use and is then discarded. The Osprey system is designed to be used with manual surgical instruments including a 2.4mm guide drill, a 5.0mm cannulated drill, and a suture passer to aid in device placement. The Osprey Suture Anchor is pre-loaded on disposable inserters and provided to the end user sterile via ethylene oxide (EO) sterilization, while the reusable instruments (drills and suture passer) are non-sterile and are intended to be sterilized by the end user. The Responsive Arthroscopy Osprey Suture anchors and instrumentation are designed to accommodate an arthroscopic surgical approach.

INDICATIONS FOR USE:

The Osprey Suture Anchor is intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, and elbow in the following procedures:

- Shoulder: Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Meniscal Root Repair. Secondary fixation for ACL/PCL reconstruction.
- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

TECHNOLOGICAL CHARACTERISTICS:

The subject Osprey Suture Anchors have the same intended use and fundamental scientific technology as the predicate devices cleared under K173845 and K180951. The subject devices and the predicate devices feature similar technological characteristics as the predicate devices, including a knotless PEEK anchor design, principles of operation, 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 Osprey Suture Anchor indications for use are similar to both predicate devices (K173485 and K180951). The subject device indications are a subset of the predicate indications that includes the procedures and anatomic locations deemed appropriate based on the design of the subject device. Each of the subject Osprey device labeled indications for use are present in one or both of the predicate devices, and therefore the noted differences do not constitute a new intended use for the subject device, nor do the differences affect device safety and effectiveness. Thus, the subject device intended use remains identical to the predicate devices: fixation of soft tissue to bone.

The subject device features slight differences in technology as compared to the predicate devices, including anchor body design, anchor body dimensions, insertion method, and suture locking 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 Osprey Suture Anchors have the same intended use and fundamental scientific technology as the predicate devices, while having similar indications for use and technological characteristics. The differences in technology do not raise different questions of safety or efficacy. Therefore, the Osprey Suture Anchors are substantially equivalent to the predicate devices.

PERFORMANCE TESTING:

Nonclinical performance testing was completed to demonstrate that the Osprey 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. 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 Suture Locking Force Testing
- Cyclic Pullout Force Testing

In summary, performance testing of the Osprey 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 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.