July 20, 2026

Responsive Arthroscopy, Inc.
Gretchen Hinchley
Executive VP of Operations
701 N. 3rd St.
Suite 208
Minneapolis, Minnesota 55401

Re: K261632
Trade/Device Name: Thunderbolt System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: May 15, 2026
Received: May 18, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261632

Please provide the device trade name(s).

Thunderbolt System

Please provide your Indications for Use below.

The Thunderbolt System is intended for soft tissue to bone fixation for the following indications:

Shoulder: Bankart lesion repair, SLAP lesion repairs, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps Tenodesis

Foot and Ankle: Medial/lateral repair and reconstruction, Mid-and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair, Ankle Syndesmosis fixation (Syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures

Elbow: Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment

Knee: ACL/PCL repair/ reconstruction, ACL/PCL patellar bone-tendon-bone grafts, Double-Tunnel ACL reconstruction, Extracapsular repair: MCL, LCL, and posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure

Hand and Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, Tendon transfers in phalanx, Volar plate reconstruction

Hip: Acetabular labral repair

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) SUMMARY

DATE PREPARED: May 15, 2026

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

ESTABLISHMENT REGISTRATION: 3015200759

CONTACT INFORMATION:
Gretchen Hinchley
Executive VP of Operations
(612) 867-6795
Ghinchley@responsivesports.com

DEVICE INFORMATION:

Trade Name:	Thunderbolt System
Common Name:	Suture Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Product Code:	MBI, JDR
Classification:	Class II
Regulation Number:	21 CFR 888.3040
Primary Predicate Device:	Responsive Arthroscopy Thunderbolt System (K203121)
Reference Device:	Responsive Arthroscopy Shadow Knotless All-Suture Anchors (K233258)

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

DEVICE DESCRIPTION:

The Thunderbolt System is a knotless fixation system intended for the fixation of soft tissue to bone and consists of a suture-button implant assembly and an implantable two-holed plate. The system is offered in titanium per ASTM F136 or 316L stainless steel per ASTM F138/F139. It features a distal button, a fibula button, a high-strength suture assembly that connects the two buttons, and an optional washer that may be used with the suture assembly. The suture-button implant system is designed to secure suture material between the two buttons positioned on opposing sides of adjacent bone structures. Once deployed and tensioned, the system maintains physiological reduction to support healing. Each Thunderbolt System is intended for use with manual surgical instrumentation, including drills and drill guides. All Thunderbolt Systems are provided as single-use devices and are sterilized using ethylene oxide (EO) sterilization.

INDICATIONS FOR USE:

The Thunderbolt System is intended for soft tissue to bone fixation for the following indications:

- Shoulder: Bankart lesion repair, SLAP lesion repairs, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps Tenodesis
- Foot and Ankle: Medial/lateral repair and reconstruction, Mid-and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair, Ankle Syndesmosis fixation (Syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures
- Elbow: Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment
- Knee: ACL/PCL repair/ reconstruction, ACL/PCL patellar bone-tendon-bone grafts, Double-Tunnel ACL reconstruction, Extracapsular repair: MCL, LCL, and posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure
- Hand and Wrist: Collateral ligament repair, Scapholunate ligament reconstruction, Tendon transfers in phalanx, Volar plate reconstruction
- Hip: Acetabular labral repair

TECHNOLOGICAL CHARACTERISTICS:

The subject Thunderbolt System has the same intended use and fundamental scientific technology as the predicate device cleared under K203121. The subject device features similar technological characteristics as the predicate device, including suture-button design, knotless design, principles of operation, materials, suture, performance specifications and characteristics, packaging and shelf life, and sterilization method. In addition, both the subject device and predicate device are provided sterile and single use only.

The subject device features slight differences in technology as compared to the predicate device, including the addition of a stainless steel implant option, updates to the fibula button design (dimensions and geometry), an updated suture material, a modified insertion trocar/needle, inclusion of a washer, updated packaging, and the incorporation of a disposable silicone suture handle to facilitate tensioning of the assembly. 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 Thunderbolt System has the same intended use, indications for use, and fundamental scientific technology as the predicate devices. The minor differences in technology do not raise different questions of safety or efficacy. Therefore, the subject Thunderbolt System is substantially equivalent to the predicate device.

PERFORMANCE TESTING:

Nonclinical performance testing was completed to demonstrate that the subject Thunderbolt met the established performance characteristics and design requirements. Performance testing consisted of design verification testing (bench testing) that included comparison to the predicate device. All testing met acceptance criteria and demonstrated that the device met design specifications and performed as intended.

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

- Cyclic Pullout Force Testing
- Suture Characterization Testing

In summary, performance testing of the Thunderbolt System indicated no new risks and demonstrated substantial equivalence in performance compared to the legally marketed predicate device.

CONCLUSION:

In conclusion, the subject device has the same intended use, indications for use, and fundamental scientific technology as the predicate device. The differences in technological characteristics 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 device. Therefore, the subject device is substantially equivalent to the predicate device.