May 1, 2026

ArthroTAK, LLC
% Ken Riordan
Regulatory Consultant
RPC Consulting LLC
15183 Harrison Lake Cove
Fort Wayne, Indiana 46814

Re: K252635
Trade/Device Name: ArthroTAK Tendon Anchor Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 31, 2026
Received: March 31, 2026

Dear Ken Riordan:

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, 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

# 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. | K252635 |

Please provide the device trade name(s).

ArthroTAK Tendon Anchor Kit

Please provide your Indications for Use below.

The ArthroTAK Tendon Anchor Kit is intended to be used for soft-tissue to bone fixation in biceps tenodesis shoulder procedures.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252635

# 510(k) Summary

Prepared on: 2026-03-31

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | ArthroTAK, LLC |
| Applicant Address | 2925 Stockyard Rd Suite B Missoula MT 59808 United States |
| Applicant Contact Telephone | 574-253-1133 |
| Applicant Contact | Mr. Don Running |
| Applicant Contact Email | don.running@exodusnewventures.com |
| Correspondent Name | RPC Consulting, LLC |
| Correspondent Address | 15183 Harrison Lake Cv Fort Wayne IN 46814 United States |
| Correspondent Contact Telephone | 815-388-3058 |
| Correspondent Contact | Mr. Ken Riordan |
| Correspondent Contact Email | kenneth.riordan@outlook.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | ArthroTAK Tendon Anchor Kit |
| Common Name | Smooth or threaded metallic bone fixation fastener |
| Classification Name | Fastener, Fixation, Nondegradable, Soft Tissue |
| Regulation Number | 888.3040 |
| Product Code(s) | MBI |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K260004 | Aevumed PROTEKT Suture Anchor | MBI |
| K143037 | SnapShot Fixation System | JDR |

## Device Description Summary

21 CFR 807.92(a)(4)

The ArthroTAK Tendon Anchor Kit consists of an ArthroTAK implant and inserter. The ArthroTAK implant is a poly-ether-etherketone (PEEK) anchor comprised of two components, a proximal tack and distal bullet. The ArthroTAK inserter comes pre-loaded with the ArthroTAK implant and is designed to enable insertion of the ArthroTAK implant into the bone. A single-use bone punch is available and can be used to create a pilot hole for insertion in hard bone.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ArthroTAK Tendon Anchor Kit is intended to be used for soft-tissue to bone fixation in biceps tenodesis shoulder procedures.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

Both the subject device and predicate device are intended for use for soft tissue fixation in bicep tenodesis procedures.

## Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics (materials, design, sizing, and indications) of the ArthroTAK Tendon Anchor Kit are similar or identical to the predicate device or reference device.

• Materials: The proposed ArthroTAK Tendon Anchor Kit utilizes the same implant material, polyetheretherketone (PEEK), as the predicate device (K260004).

• Design Features: The proposed ArthroTAK Tendon Anchor Kit has the same design features and is dimensionally similar to the device, SnapShot Fixation System (K143037).

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following nonclinical evaluations were conducted to support substantial equivalence:
-Insertion Testing per ASTM F3690-24
-Pullout Testing
-Component Interconnection Evaluation
-Fatigue & Pull-to-failure testing per ASTM 3690-24
-Sterilization Validation per ISO 11137-1:2006, ISO 11137-2:2013, and ISO 1137-3:2017
-Biological Evaluation per ISO 10993-1:2018

Not Applicable

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.