January 28, 2026

Aevumed, Inc.
Saif Khalil
CEO
109 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K260004
Trade/Device Name: Aevumed PROTEKT™ 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 30, 2025
Received: January 2, 2026

Dear Saif Khalil:

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,

Thomas Mcnamara -S

For: 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

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)*

K260004

Device Name

Aevumed PROTEKT Suture Anchor

Indications for Use *(Describe)*

The Aevumed PROTEKT™ Suture Anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:

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

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

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all Digits, Digital Tendon Transfers

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

Hip: Capsular repair, Acetabular Labral 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification 510(k) Summary

MANUFACTURER / SPONSOR:	Aevumed Inc. 109 Great Valley Parkway Malvern, PA 19355
CONTACT:	Saif Khalil, Ph.D. Chief Operating Officer Phone: (610) 601-6614 email: skhalil@aevumed.com
DATE PREPARED:	December 30th, 2025
TRADE NAME:	Aevumed PROTEKT™ Suture Anchor
COMMON NAME:	Suture Anchor
DEVICE CLASSIFICATION:	Smooth or threaded metallic bone fixation fasteners, classified as Class II, product code: MBI, Regulation 21 CFR 888.3040
PRIMARY PREDICATE DEVICE:	Aevumed FASE™ Suture Anchor, 510(k) number K253040
ADDITIONAL PREDICATE DEVICES:	Aevumed PHANTOM™-LP Suture Anchor, 510(k) number K222363 Aevumed PHANTOM™ Suture Anchor, 510(k) number K180464
DEVICE DESCRIPTION:	The Aevumed PROTEKT™ Sutures Anchor with HS Fiber™ suture is a suture anchor manufactured from polyetheretherketone (PEEK) material and are preloaded on a disposable inserter assembly intended for fixation of soft tissue to bone. The Aevumed PROTEKT™ Suture Anchors is available in diameter size: 6.5 mm. It is offered sterile and is for single use only.

TECHNOLOGICAL CHARACTERISTICS:	The proposed PROTEKT™ Suture Anchor with HS Fiber™ suture is similar to the predicate FASE™ Anchor (K253040) in that they share the same intended use, material, operational principle, sterilization method, packaging, and shelf life. The minor differences between the modified PROTEKT™ Suture Anchor and predicate FASE™ Anchor (K253040) do not raise new questions of safety and effectiveness.
INDICATIONS FOR USE:	The Aevumed PROTEKT™ Suture Anchors are intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below: -Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction -Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction -Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis -Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all Digits, Digital Tendon Transfers -Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction -Hip: Capsular repair, Acetabular Labral Repair
POPULATION:	Patients age 18 and older. Contraindication: Not for use across growth plates in patients who are not skeletally mature. The Aevumed PROTEKT™ Suture Anchor is prescribed by the physician.
NON-CLINICAL TESTS:	Mechanical performance testing was not conducted for the subject suture anchor. Justifications were provided to demonstrate that the subject suture anchor does not represent a new worst case as compared to the predicates from a mechanical performance perspective.

The major design difference between the subject device and the predicate device is an increase in anchor diameter. This dimensional change does not introduce a new mode of failure and is not expected to negatively impact the mechanical integrity or functional performance of the device.

CONCLUSIONS: The Aevumed PROTEKT™ Suture Anchor is substantially equivalent to the predicate devices. Any differences between the Aevumed PROTEKT™ Suture Anchor and the predicate devices are considered minor and do not raise questions concerning safety and efficacy.