March 17, 2023

Aevumed, Inc.
Saif Khalil, Ph.D.
President & CEO
109 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K223878
Trade/Device Name: Aevumed RAPID™ 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: December 23, 2022
Received: December 27, 2022

Dear Dr. 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 (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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
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)*
K223878

Device Name
Aevumed RAPID™ Suture Anchors

Indications for Use *(Describe)*
The Aevumed RAPID™ 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.

5. 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:	March 5th, 2023
TRADE NAME:	Aevumed RAPID™ 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:	SutureTak™ Suture Anchor, 510(k) number K140855
REFERENCE PREDICATE DEVICE:	Aevumed RAPID™ Suture Anchor, 510(k) number K180464
DEVICE DESCRIPTION:	The Aevumed RAPID™ Suture Anchor with HS Fiber™ suture is a suture anchor manufactured from polyetheretherketone (PEEK) material preloaded on a disposable inserter assembly intended for fixation of soft tissue to bone. The Aevumed RAPID™ Suture Anchors are available in diameter sizes: 2.4mm and 3.0mm. They are offered sterile and are for single use only.

TECHNOLOGICAL CHARACTERISTICS:	The proposed RAPID™ Suture Anchors with HS Fiber™ suture is similar to the predicate SutureTak™ Anchor (K140855) in that they share the same intended use, geometric design, material, operational principle, sterilization method, packaging, and shelf life. The minor differences between the modified RAPID™ Suture Anchors and predicate SutureTak™ Anchor (K140855) do not raise new questions of safety and effectiveness.
INDICATIONS FOR USE:	The Aevumed RAPID™ 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
INTENDED POPULATION:	Patients age 18 and older. Contraindication: Not for use across growth plates in patients who are not skeletally mature. The Aevumed RAPID™ Suture Anchor is prescribed by the physician.
NON-CLINICAL TESTS:	The substantial equivalence is bases on non-clinical data. Both the Aevumed RAPID™ Suture Anchor and predicate SutureTak™ Anchor (K140855) were mechanically tested for maximum pullout strength. The Aevumed RAPID™ Suture Anchor demonstrated

significantly higher pullout strength in comparison to the predicate SutureTak™ Anchor (K140855).

The sterilization, packaging, pyrogenicity/endotoxin monitoring, biocompatibility, and shelf life of the Aevumed RAPID™ Suture Anchor are identical to the predicate device Aevumed RAPID™ Suture Anchor (K180464).

SAFETY& PERFORMANCE:

The Aevumed RAPID™ Suture Anchor is substantially equivalent to the predicate device. The data support the safety of the device and demonstrate that the Aevumed RAPID™ Suture Anchor device should perform as intended in the specified use conditions and performs comparably to the predicate device that is currently marketed for the same intended use. Any differences between the Aevumed RAPID™ Suture Anchor and the predicate device are considered minor and do not raise questions concerning safety and efficacy.