May 31, 2018

Aevumed, Inc.
% Carol Rutkowski
Partner, Pyxa Solutions
Pyxa Solutions LLC
1034 West Thomas Road
Plymouth Meeting, Pennsylvania 19462

Re: K180464
Trade/Device Name: AEVUMED PHANTOM 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: April 30, 2018
Received: April 30, 2018

Dear Ms. Rutkowski:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180464

Device Name
AEVUMED PHANTOM Suture Anchors

Indications for Use *(Describe)*
The Aevumed PHANTOM™ suture anchors are intended to be used for suture and/or soft tissue fixation to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in, but not limited to, the following procedures:

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

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

• Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair and Illiotibial Band Tenodesis.

• Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.

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

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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5. Premarket Notification 510(k) Summary

MANUFACTURER / SPONSOR:	Aevumed Inc. 877 Richards Rd. Wayne, PA 19807
CONTACT:	Saif Khalil, Ph.D. Chief Operating Officer Phone: (610) 745-7284 Fax: (610) 783-0307
TRADE NAME :	Aevumed PHANTOM™ 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 .
PREDICATE DEVICE:	Arthrex Corkscrew FT, 510(k) number K061665.

DEVICE DESCRIPTION:

The Aevumed PHANTOM™ Anchor with HS Fiber™ suture is a threaded suture anchor manufactured from polyetheretherketone (PEEK) material preloaded on a disposable driver assembly intended for fixation of soft tissue to bone. The Aevumed PHANTOM™ Anchor with HS Fiber™ are pre-loaded with or without needles. The Aevumed PHANTOM™ Suture Anchor are available in diameter sizes: 5.5mm and 6.5mm. They are offered sterile and are for single use only.

TECHNOLOGICAL CHARACTERISTICS: The proposed Aevumed PHANTOM™ Anchors with HS Fiber™ suture are similar to the predicate Arthrex Corkscrew FT (K061665) in that they share the same intended use, have the same anchor materials and principal operation . The devices do not raise different questions of safety and effectiveness.

INDICATIONS FOR USE: The Aevumed PHANTOM™ suture anchors are intended to be used for suture and/or soft tissue fixation to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow in, but not limited to, the following procedures:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair.
- Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair and Illiotibial Band Tenodesis.
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.
- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

INTENDED POPULATION: Patients age 18 and older. Contraindication: Not for use across growth plates in patients who are not skeletally mature. The Aevumed PHANTOM™ suture anchor is prescribed by the physician.

NON-CLINICAL TESTS: The substantial equivalence is based on non-clinical data. Both the Aevumed PHANTOM™ suture anchor and predicate device were mechanically tested for the following;

- Torsional Strength
- Driving torque
- Pullout Strength.

SAFETY& PERFORMANCE**:**

The Aevumed PHANTOM™ Anchor is substantially equivalent to the Arthrex Corkscrew FT Suture Anchor. The data support the safety of the device and demonstrate that the Aevumed PHANTOM™ 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 PHANTOM™ suture anchor and the Arthrex Corkscrew FT are considered minor and do not raise questions concerning safety and efficacy.