March 26, 2020

Valeris Medical Inc.
Brendan Thies
Medical Device Engineer
200 Cobb Pkwy N, Building 200, Suite 210
Marietta, Georgia 30062

Re: K193108
Trade/Device Name: Bonecam 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: October 21, 2019
Received: November 8, 2019

Dear Mr. Thies:

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,

for

Jesse Muir, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193108

Device Name
Bonecam Suture Anchor

Indications for Use *(Describe)*

Shoulder
- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acormio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift or Capsulolabral Reconstruction

Hand and 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

Foot and 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
- Posterior oblique ligament repair
- Illiotibial band tenodesis reconstruction
- Patellar ligament/tendon 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.

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510(k) Summary

(as required by 21 CFR 807.92)

Date Prepared	March 24, 2020
Manufacturer	Valeris Medical
Address	200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 105
Fax	770-575-4052
Contact Person	Brendan Thies Medical Device Engineer
Address	Valeris Medical 200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 105
Fax	770-575-4052
Email	Brendan@Valerismedical.com

Trade Name	Bonecam Suture Anchor
Common Name	Screw, Fixation, Bone
Panel Code	Orthopaedics/87
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	MBI

Name of Predicate Device	**510(k) #**	**Manufacturer**
Bonecam Suture Anchor	K152255	Valeris Medical
Reference Predicate Device	**510(k) #**	**Manufacturer**
Riverpoint HS Fiber Suture	K100006 K190817	Riverpoint Medical

Description	The BoneCam Suture Anchor Delivery Systems are for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The BoneCam Suture Anchor Delivery System consists of a single anchor with integrated multiple suture attachment. The anchors are provided loaded on individual inserters with integrated sutures with or without needles, sterile (EtO), for single use only. The BoneCam Suture Anchor Delivery Systems have a shelf life of 2 years. Implants are fabricated from Solvay Zeniva ZA-500, ZA-600, or ZA-600 CF30 PEEK (ASTM F2026).
Modifications for FDA 510(k) Review	•Add a set of Bonecam anchors made from ZA-600 CF30 (same MAF file as filed in predicate device) •Add a configuration that allows surgeons to load additional suture into the device •Add a set of Bonecam anchors made from ZA-600 PEEK •Add an additional Suture manufacture for UHMWPE suture and tape products

Indications and Intended Use	Shoulder • Rotator Cuff Repair

	• Bankart Repair • SLAP Lesion Repair • Biceps Tenodesis • Acormio-Clavicular Separation Repair • Deltoid Repair • Capsular Shift or Capsulolabral Reconstruction Hand and 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 Foot and 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 • Posterior oblique ligament repair • Illiotibial band tenodesis reconstruction • Patellar ligament/tendon repair

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, Bonecam Suture Anchor is substantially equivalent to the Predicate Bonecam Suture Anchor (K152255). The Subject device is substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, performance and labeling. Materials: The subject device is very similar to the predicate device in that they are both fabricated from Solvay ZENIVA PEEK; the subject device will offer additional configurations Solvay Zeniva PEEK (ZA-600 and ZA-600 CF). An additional suture manufacturer is being proposed that will provide UHMWPE sutures that are substantially equivalent to those used in the predicate device. Design Features: The additional configuration of the subject device anchor is the same design as the predicate with an additional suture port to provide additional options for the type of suture used with the anchor. Sterilization and Shelf-Life: The subject and predicate devices are offered sterile (EtO), and have a shelf-life of 2 years.

	Biocompatibility: Biocompatibility was established according to ISO 10993-1. Bacterial endotoxins for the implantable components are determined using LAL testing to meet endotoxin limit specifications. Additional instrument modifications include change of material for the Obturator (stainless steel, Drill Guide (stainless steel), and the Instrument Handle (Radel). There were also design modifications to the Small Joint Inserter Handle to incorporate the suture and needles within the handle. The subject device is substantially equivalent to the predicate device in that they are comprised of similar materials, share the same fundamental technology, are intended for the same indications and utilize similar designs. They are capable of achieving fixation in the same way.
Performance Data	Axial Pull-Out per ASTM F543-17 testing was conducted to confirm the material additive did not introduce any new risk.
Conclusion	Based on the intended use, indications for use, technological characteristics, and comparison to the predicate device, the Subject device has been shown to be substantially equivalent to the legally marketed predicate device and is safe and effective for the intended use.