DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Valeris Medical
% Ms. Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
P.O. Box 15729
Wilmington, North Carolina 28408

November 16, 2015

Re: K152255
Trade/Device Name: BoneCam 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: August 18, 2015
Received: August 19, 2015

Dear Ms. Wagoner:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152255

Device Name
BoneCam Suture Anchor

Indications for Use *(Describe)*
Valeris BoneCam Suture Anchors are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.

Shoulder
Rotator Cuff Repair
Bankart Repair
SLAP Lesion Repair
Biceps Tenodesis
Acormio-Clavicular Separation Repair
Deltoid Repair
Capisular 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
Posterior Oblique Ligament Repair
Iliotibial Band Tenodesis Reconstruction
Patellar Ligament/Tendon Repair

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K152255

510(k) Summary
(as required by 21 CFR 807.92)

Date Prepared	11/12/2015
Manufacturer	Valeris Medical
Address	200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188
Contact Person	Daniel Lanois President
Address	Valeris Medical 200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188
email	daniel@valerismedical.com

Trade Name	BoneCam Suture Anchor
Common Name	Suture Anchor
Panel Code	Orthopaedics/87
Classification Name	Smooth or threaded metallic bone fixation fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	MBI

Name of Predicate Device	**510(k) #**	**Manufacturer**
Arthrex SutureTak® Suture Anchors	K140855	Arthrex Inc.
Valeris Apollo Suture Anchor System and Titan Screws	K142230	Valeris

Description	The BoneCam Suture Anchor Delivery Systems are delivery systems for anchors for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, hip, and hand/wrist procedures. These anchors consist of anchors with integrated suture attachment. The Anchors are provided loaded on individual inserters with integrated UHMWPE sutures. Sterile, for single use only. Anchor implants are made from either a titanium alloy (6Al4V ELI) per ASTM F136, or PEEK (Zeniva ZA-500) per ASTM F2026 from Solvay Advanced Polymers. Anchors range in size from 2.9mm to 3.3mm in diameter and 6mm to 10mm in length.

Indications and Intended Use	Valeris BoneCam Suture Anchors are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. **Shoulder** Rotator Cuff Repair Bankart Repair SLAP Lesion Repair Biceps Tenodesis

	Acormio-Clavicular Separation Repair Deltoid Repair Capisular 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 Posterior Oblique Ligament Repair Iliotibial Band Tenodesis Reconstruction Patellar Ligament/Tendon Repair **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

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, Valeris BoneCam Suture Anchor is substantially equivalent to the Predicate Arthrex Suture Tak® Suture Anchors (K140855). The Subject device is substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, and labeling.

Performance Data	Axial Pull-Out per ASTM F543-13 testing confirmed that the Subject device performed as intended with #2, 2-0, 3-0, and 4-0 sutures in G20 PU foam and in G40 PU foam for #2 sutures.

Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and comparison to predicate devices, the Subject Valeris BoneCam Suture Anchor (Subject device) has been shown to be substantially equivalent to legally marketed predicate devices.