



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Cayenne Medical, Incorporated  
Shima Hashemian  
RA/QA Director  
16597 N 92nd Street, Suite 101  
Scottsdale, Arizona 85260

July 24, 2015

Re: K151068

Trade/Device Name: Surelock™ W 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: July 6, 2015  
Received: July 14, 2015

Dear Shima Hashemian:

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.

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" (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.

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

~~XXXXXXXXXX~~  
K151068

Indications for Use

Device Name: SureLock™ W Suture Anchor

Indications for Use:

The Cayenne Medical, Inc. SureLock™ W Suture Anchors is intended to be used for the reattachment of soft tissue to bone in rotator cuff repairs.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Summary****Cayenne Medical, Inc.**  
SureLock™ W Suture Anchor**Administrative Information**

Date of summary: 04/16/2015

Manufacturer Name: Cayenne Medical, Inc.  
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**Device Name**

Classification Name: Smooth or threaded metallic bone fixation fastener

Trade/Proprietary Name: SureLock™ W Suture Anchor

Common Name: Suture Anchor

**Device Classification**

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for Fastener, Fixation, Nondegradable, and Soft Tissue is MBI.

**Device Description**

The SureLock™ W Suture Anchor is a sterile, manually operated, single procedure suture anchor device for reattachment of soft tissue to bone. The suture anchor is preloaded with floating suture and loaded on a disposable inserter. The SureLock™ W Suture Anchor incorporates design features that facilitate suture anchor placement under arthroscopic, open, or limited access conditions in soft tissue to bone reattachment procedures.

The SureLock™ W Suture Anchor is offered in one size, 2.5mm. The anchors are made out of non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE) surgical suture, PolyEtherEtherKetone (PEEK), and L-lactide/glycolide copolymer (PLGA). The floating sutures are made out of size 2 non-absorbable UHMWPE surgical sutures. The suture anchor is pre-loaded with two floating sutures.

The disposable inserter has a working shaft length of 22.2 cm with an outer shaft diameter of 4.6mm. The inserter shaft is made out of surgical grade stainless steel and the handle and knob are made out of ABS plastic. The inserter pushes the suture anchor into a hole drilled in the bone. The knob on the inserter handle is rotated to apply tension to the floating sutures to expand and deploy the anchor in the bone tunnel. When the knob is fully rotated, the floating suture limbs are released from the inserter and the inserter is removed.

**Intended use**

The Cayenne Medical, Inc. SureLock™ W Suture Anchor is intended to be used for the reattachment of soft tissue to bone in rotator cuff repairs.

**Technological Differences**

The SureLock™ W Suture Anchor is similar in indications for use, intended use, design features, technology, and materials to the predicate device.

The subject SureLock™ W device has the same intended use as the predicate device, the Cayenne Medical SureLock™ All-Suture Anchor. The predicate device has a broader indication for use compared to the subject device. The subject device is only indicated for soft tissue to bone attachment in rotator cuff repairs but the predicate device is indicated for soft tissue to bone attachment in shoulder, foot and ankle, elbow, hand and wrist, hip, and knee procedures. Cayenne Medical tested both predicate and subject devices for the subject device indication using two bone block densities.

The subject device differs from the predicate device, Cayenne Medical SureLock™, in terms of the anchor materials, design features (wick component), and the offered sizes.

**Non-clinical Testing**

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. The results of performance testing, including biocompatibility, and mechanical testing demonstrated that the functionality and safety of the SureLock™ W Suture Anchor are adequate for its intended use and determination of substantial equivalence to the predicate device.

**Clinical Testing**

Clinical testing was not used to establish substantial equivalence to predicate device.

**Equivalence to Marketed Product**

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the SureLock™ W Suture Anchor is substantially equivalent in indication and design principles to the predicate device, which has been determined by FDA to be substantially equivalent to preamendment devices: Cayenne Medical SureLock™ All-Suture Anchor (K132867). The substantial equivalence of SureLock™ W Suture Anchor is based on similarities in indications for use, intended use, design features, technology, and materials to the predicate device.