Cayenne Medical, Inc.
Ms. Shima Hashemian
QA/RA Associate Director
16597 N. 92nd Street, Suite 101
Scottsdale, Arizona 85260

October 16, 2017

Re: K172186
Trade/Device Name: BioWick™ X Implant with Driver
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 19, 2017
Received: July 20, 2017

Dear Ms. 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock
-S

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

Enclosure

Indications for Use

Device Name: BioWick™ X Implant with Driver

Indications for Use:

The Cayenne Medical, Inc. BioWick™ X Implant is intended to be used for the reattachment of soft tissue to bone in rotator cuff repairs.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Cayenne Medical, Inc.

BioWick™ X Implants and Driver

Administrative Information

Date of summary:	07/19/2017
Manufacturer Name:	Cayenne Medical, Inc. 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Telephone (480) 502-3661 FAX (480) 502-3670
Official Contact:	Shima Hashemian 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Shima.Hashemian@zimmerbiomet.com Telephone (480) 502-3661 FAX (480) 502-3670

Device Name

Classification Name:	Smooth or threaded metallic bone fixation fastener
Trade/Proprietary Name:	BioWick™ X Implant with Driver
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 BioWick™ X Implant is a sterile, manually operated, single procedure implant device for reattachment of soft tissue to bone. The implant is preloaded with floating suture and loaded on a disposable driver. The BioWick™ X implant incorporates design features that facilitate implant placement under arthroscopic, open, or limited access conditions in soft tissue to bone reattachment procedures.

The BioWick™ X implant is offered in two sizes, 5.5 mm and 6.5 mm. The implant is made out of PolyEtherEtherKetone (PEEK), L-lactide/glycolide copolymer (PLGA), and Ultra High Molecular Weight Polyethylene (UHMWPE). The floating sutures are size 2 non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE) surgical sutures. The implant is either preloaded with two or three surgical sutures.

The disposable driver has a working shaft length (from handle to distal tip of anchor) of 6.24 in (158mm) with an outer shaft diameter of 0.159 in (4.0mm). The driver shaft is made out of surgical grade stainless steel and the handle is made out of ABS plastic. The driver facilitates the placement of the implant into a hole tapped in the bone.

Intended use

The Cayenne Medical, Inc. BioWick™ X Implant is intended to be used for the reattachment of soft tissue to bone in rotator cuff repairs.

Technological Differences

The BioWick™ X Implant is similar in its indication for use, intended use, design features, technology, and materials to the predicate device.

The subject BioWick™ X device has the same intended use and indication for use as the predicate device, the Cayenne Medical BioWick™ SureLock® Implant (previously named as SureLock W Suture Anchor).

The subject device differs from the predicate device, Cayenne Medical BioWick™ SureLock®, in terms of design features (number of floating sutures) and the offered sizes.

Non-clinical Testing

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. The subject device was tested to be non-pyrogenic, assessed for biocompatibility, validated sterility, and performed mechanical and cadaveric usability testing.

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 Biowick™ X implant is substantially equivalent in indications and performance to the legally marketed predicate device, K151068 SureLock W Suture Anchor. The substantial equivalence of Biowick™ X implant is based on similarities in indications for use, intended use, design features, technology, and materials to the predicate device.