January 19, 2018

SportWelding GmbH
% Janice M. Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K171228
Trade/Device Name: Fiji Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, HTY, GAT
Dated: December 13, 2017
Received: December 13, 2017

Dear Ms. Hogan:

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,

Katherine D. Kavlock -S

for
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K171228

Device Name

Fiji Anchor

Indications for Use *(Describe)*

The Fiji Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, wrist, elbow, and shoulder. The Fiji Anchor is designed only to be inserted with the BoneWelder 150-W1 system. Specific indications are listed below:

Elbow: Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Bankart Repair, Capsular Shift or Capsulolabral Reconstruction

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

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot 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.

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K171228

510(k) SUMMARY

SportWelding's Fiji Anchor

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sport Welding GmbH
Wagistrasse 6
Schlieren, Switzerland

Phone: +41 44 204 61 2821
Facsimile: +41 44 204 61 2820
Contact Person: Joerg Mayer, Managing Director, CTO

Date Prepared: January 17, 2018

Name of Device and Name

Fiji Anchor

Common or Usual Name

Fastener, fixation, biodegradable, soft tissue (MAI), class II

Pin, fixation, smooth (HTY), class II

Suture, nonabsorbable, synthetic, polyethylene (GAT), class II

Classification Name

Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000)

Predicate Devices

- K063479 Arthrex's Bio-PushLock (Primary)
- K143063 Stryker's SonicAnchor System (Reference)

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Technological Characteristics

The Fiji anchor system consists of an implantable anchor, an ultrasound system, and handpiece tip, and a twist drill.

The Fiji Anchor® is made of biocompatible and fully bioresorbable Poly-L-lactide-co-D,L-lactide. The in vivo degradation of the Fiji Anchor® is based on the natural physiologic process of hydrolysis, which results in the complete metabolization of the polymer into H_2O and CO_2.

The Fiji Anchor® is a fully bioresorbable implant designed for soft tissue reattachment to bone by means of suture material. The BoneWelding® technology employs ultrasonic energy to liquefy the polymeric components of the Fiji Anchor® at the interface with bone tissue. The liquid polymer flows into the marrow space of the surrounding cancellous bone where it is immediately quenched and provides anchorage of the implant.

The ultrasonic energy for the implantation of the Fiji Anchor® is produced by the BoneWelder® ultrasonic generator and applied via the attached handpiece. The handpiece tip (sonotrode) is mounted on the handpiece. It transmits the ultrasonic energy to the Fiji Anchor®. The twist drill is dedicated to be used with the Fiji Anchor®.

Performance Data

The following tests were performed to demonstrate the substantial equivalence of the Fiji Anchor:

- Software documentation and validation per FDA guidance
- IEC 60601-1 and 60601-1-2 testing
- Material characterization using GPC, inherent viscosity, GCMS, and ICP
- Static pullout testing before and after aging
- Dynamic pullout testing before and after aging
- Creep testing
- Extraction and analysis per ISO 10993-18

- Cytotoxicity testing per ISO 10993-5
- Temperature rise in surrounding bone (porcine bone)
- Lot-to-lot endotoxin testing is also performed per USP <85>

Substantial Equivalence

The Fiji Anchor is as safe and effective as the Arthrex's Bio-PushLock. The Fiji Anchor has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Fiji Anchor and its predicate devices, summarized in the table below, raise no new issues of safety or effectiveness. Performance data demonstrate that the Fiji Anchor is as safe and effective as Arthrex's Bio-PushLock. Thus, the Fiji Anchor is substantially equivalent.

Property	SportWelding Fiji Anchor	Arthrex 2.5 mm Bio-PushLock	Stryker Sonic Anchor
510(k)	Subject	K063497	K143063
Components	Anchor, suture, sonotrode, US generator	PEEK eyelet, suture, anchor	Anchor, suture, sonotrode, US generator
Size	2.3 x 7.2 mm	2.5 x 8 mm	2.5 x 12 mm
Suture Sizes	#4-0, #3-0, #2-0, #0, #2	#2-0, #0	#2-0, #0, #2
Insertion Method	Insert anchor into predrilled hole while applying US energy	Insert eyelet into predrilled hole, then secure with bioresorbable anchor	Partially insert anchor into predrilled hole, then fully insert while applying US energy
Fixation Method	Ultrasonic melting of the polymer into the porous cancellous bone	Barbs in a mechanical press-fit	Ultrasonic melting of the polymer into the porous cancellous bone
Length of ultrasound energy delivery	Not more than 6 seconds	N/A	Not more than 12 seconds
Suture fixation	Manual knotting	Knotless	Manual knotting
Material	PLDLLA	PLLA and PEEK	PLDLLA
Resorbable	Yes	Partly	Yes
Sterilization	Sterile	Sterile	Sterile

Conclusions

The Fiji Anchor is substantially equivalent to the predicate device.

SURGICAL FUSION TECHNOLOGIES

SportWelding GmbH is now **Surgical Fusion Technologies GmbH**

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