May 30, 2018

KATOR LLC
Robert Hoy
Director of Research
124 South 600 West, Suite 100
Logan, Utah 84321

Re: K173269
Trade/Device Name: KATOR 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: May 9, 2018
Received: May 9, 2018

Dear Mr. Hoy:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173269

Device Name

KATOR Suture Anchor

Indications for Use *(Describe)*

The KATOR Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

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.

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510(k) Summary

Device Trade Name:	KATOR Suture Anchor
Manufacturer:	KATOR LLC 124 South 600 West, Suite 100 Logan, UT 84321
Contact:	Mr. Robert Hoy Director of Research Phone: (614) 448-6358 Fax: (435) 213-4878 bob@surgicalfrontiers.com
Date Prepared:	May 9, 2018
Common Name:	Suture anchor
Classification:	21 CFR 888.3040
Class:	II
Product Code:	MBI

Indications for Use:
The KATOR Suture Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

Hip: Capsular Repair, Acetabular Labral Repair.

Device Description:
The KATOR Suture Anchor is designed to attach soft tissues to bone. It consists of an anchor body that is placed within a bone tunnel and a suture locking pin that secures soft tissue repair suture tape within the implant.

Predicate Devices:
The Arthrex, Inc., Arthrex SwiveLock Anchors (K101823), Smith & Nephew, Inc., Footprint PK Suture Anchor (K093897, K113274, K123579) and the KATOR LLC, KATOR Suture Anchor (K162386) serve as predicate devices.

Technological Characteristics Comparison:
The KATOR Suture Anchor subject device and the predicates are identical or similar in design, function, material, size and performance. The subject and predicate devices are designed to repair soft tissue by anchoring suture within a bone tunnel. The KATOR Suture Anchor subject device and both predicate devices contain UHMWPE suture material and are manufactured from PEEK, materials with well-established biocompatibility and a long history of use in many previously cleared permanent implants.

Side-by-side mechanical performance testing demonstrates that the design differences between the KATOR Suture Anchor subject device and the Arthrex SwiveLock Anchor predicate device introduce no new issues of safety or effectiveness.

Nonclinical Testing:
All necessary testing has been performed for the worst-case KATOR Suture Anchor to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of finished devices. The performance of the KATOR Suture Anchor was characterized through Insertion, Pullout Strength, Cyclic Displacement Testing. In addition pyrogenicity testing using the Limulus amebocyte lysate (BET) test, Turbidimetric Technique demonstrated the subject device meets the pyrogen limit specifications.

Clinical data were not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence:
The KATOR LLC KATOR Suture Anchor is substantially equivalent to the Arthrex, Inc., Arthrex SwiveLock Anchors (K101823), Smith & Nephew, Inc., Footprint PK Suture Anchor (K093897, K113274, K123579) and the KATOR LLC, KATOR Suture Anchor (K162386) with respect to its indications for use, design, material, size, performance and function.