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

October 25, 2016

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

Re: K162386
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: September 27, 2016
Received: September 27, 2016

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 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,

Mark N. Melkerson -S

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 below.

510(k) Number *(if known)*

K162386

Device Name
KATOR Suture Anchor

Indications for Use *(Describe)*
The KATOR Suture Anchor is intended for fixation of suture to bone in rotator cuff repairs and Achilles tendon repairs.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5. 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

Prepared by:
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: October 25, 2016

Common Name: Screw, Fixation, Bone

Classification: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Class: II

Product Code: MBI

Indications for Use:
The KATOR Suture Anchor is intended for fixation of suture to bone in rotator cuff repairs and Achilles tendon repairs.

Device Description:
The modified 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 sutures or suture tape within the implant.

Predicate Device:
The KATOR Suture Anchor (K152236) is the predicate device.

Technological Characteristics Comparison:
The modified KATOR Suture Anchor and its predicate device are offered in the same sizes and have nearly identical shapes. Both devices are generally cylindrical and have rib features on their outer diameter for engaging bone tunnel walls via an interference fit. In addition, both devices are designed to be deployed in conjunction with suture and contain suture locking pins. The modified KATOR Suture Anchor and predicate device are both manufactured from polyetheretherketone (PEEK). There are no substantial differences in technological characteristics between the two devices and as such the KATOR Suture Anchor introduces no new issues of safety or effectiveness.

Nonclinical Testing:
The subject device design was evaluated with the following verification tests, using the same methods performed on the predicate device in submission K152236:

- Static Performance Testing
- Dynamic Performance Testing

The results of this testing as summarized in the Design Control Activities Summary demonstrate that the modified KATOR Suture Anchor met the pre-determined acceptance criteria for the verification activities. Therefore, the differences between the modified and predicate devices introduce no new issues of safety or effectiveness.

Acceptable endotoxin levels were established using limulus amebocyte lysate (LAL) testing. A plan for future endotoxin monitoring was proposed.

Conclusion:
The modified KATOR Suture Anchor met all specified criteria performing as intended and did not raise any new issues of safety or effectiveness. The Indications/Intended Use and the fundamental scientific technology of the modified KATOR Suture Anchor are the same as those described in the predicate device. Based on similarities to its predicate, the modified KATOR Suture Anchor is substantially equivalent to the predicate KATOR Suture Anchor (K152236).