December 28, 2018

The Orthopaedic Implant Company
Douglas Fulton
Quality and Operations Manager
770 Smithridge Drive #400
Reno, Nevada 89502

Re: K182736
Trade/Device Name: OIC Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 28, 2018
Received: November 29, 2018

Dear Mr. Fulton:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Laurence D. Coyne -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)*
K182736

Device Name
OIC Suture Anchor System

Indications for Use *(Describe)*
The OIC Suture Anchor System is intended for fixation of soft tissue to bone and will support the following procedures:
Shoulder - Rotator cuff repair, biceps tenodesis.
Elbow - Biceps tendon reconstruction.
Knee - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar tendon repair, iliotibial band tendonesis joint capsule 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.

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.

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"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."

510(k) Summary

Prepared 11/28/2018

Name and Address of Manufacturer:
The Orthopaedic Implant Company (OIC)
770 Smithridge Drive, Suite 400
Reno, NV 89502

Contact:
Douglas Fulton
Quality Assurance Manager
Telephone: 775-636-8281
Fax: 775-636-8284
Email: doug@orthoimplantcompany.com

Device Identification:
Trade Name: OIC Suture Anchor System
Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue
Classification: Class II, 21 CFR 888.3040
Panel: Orthopedic
Product Code: MBI

Indications for Use:
The OIC Suture Anchor System is intended for fixation of soft tissue to bone and will support the following procedures:
Shoulder - Rotator cuff repair, biceps tenodesis.
Elbow - Biceps tendon reconstruction.
Knee - Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar tendon repair, iliotibial band tendonesis joint capsule repair.

Device Description:
The OIC Suture Anchor System consists of anchors and instruments to aid in implantation. The anchors are a screw-like device manufactured from PEEK plastic which are implanted into bone. Each anchor is 15mm long by 5.5mm in diameter and has an eyelet at the top that is used as an attachment point for sutures. The sutures are used to fasten soft tissues to facilitate healing. Sutures are not included in the system. Instruments include an anchor driver, 5.5mm punch/tap, suture threader and tray. The instruments are made from stainless steel and aluminum.

Comparison of Technological Characteristics (Substantial Equivalence):
Primary predicate device: K113299 RoG Sports Medicine Suture Anchor
Additional predicate: K173269 Kator Suture Anchor
The OIC Suture Anchor System has the following similarities to those which previously received 510(k) concurrence: has the same intended use, uses the same operating principle, and incorporates the same or similar materials

Performance Testing:
Mechanical testing was conducted to ascertain that the suture anchors have acceptable characteristics for the intended uses.

Conclusion:
The OIC Suture Anchor System described in this submission is, in our opinion, substantially equivalent to the predicate devices.