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

May 5, 2016

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

Re: K153585
Trade/Device Name: Flip Button 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: March 28, 2016
Received: March 29, 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 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 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 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 yours,

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)*
K153585

Device Name
First Ray Flip Button Suture Anchor

Indications for Use *(Describe)*
The First Ray Flip Button Suture Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, and wrist. Specific indications are listed below:

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, Achilles Tendon Repair, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K153585

Device Trade Name: Flip Button Suture Anchor

Manufacturer:
First Ray LLC
124 South 600 West, Suite 100
Logan, UT 84321

Contact:
Mr. Robert Hoy
Director of Research
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Prepared by:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
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Phone: (202) 552-5800
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Date Prepared: April 22, 2016

Common Name: Fastener, Fixation, Soft Tissue

Classification: 21 CFR 888.3040

Class: II

Product Code: MBI

Indications for Use:
The First Ray Flip Button Suture Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, and wrist. Specific indications are listed below:

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, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-Foot Reconstruction

Device Description:
The Flip Button Suture Anchor is a device which is preloaded with suture and is designed to attach soft tissues to bone. The device is deployed through a bicortical drill hole and secured on the far cortex.

Predicate Devices:
Arthrex Tak (K050749 & K061863)
Mitek MINILOK QuickAnchor Plus (K030995)

Technological Characteristics Comparison:
The Flip Button Suture Anchor and its predicate device are similar in size and material. Both devices are loaded with suture and designed to engage a bone tunnel and anchor the suture within the bone. The Flip Button Suture Anchor and predicate device families contain implants manufactured from polyetheretherketone (PEEK). The Flip Button Suture Anchor is also offered in a titanium 6Al-4V ELI conforming to ASTM F136. This is a material with superior strength to PEEK and a long history of biocompatibility and use in previously cleared permanent implants. There are no substantial differences in technological characteristics between the two devices and as such the Flip Button Suture Anchor introduces no new issues of safety or effectiveness.

Nonclinical Testing:
All necessary testing has been performed for the worst-case Flip Button Suture Anchor to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. The Flip Button Suture Anchor performance was characterized through static pullout testing in bone analog material with a side-by-side comparison to the predicate device. Clinical data were not needed to support the safety and effectiveness of the subject device.

Conclusion:
The Flip Button Suture Anchor is substantially equivalent to the Arthrex Tak (K050749 & K061863) and Mitek MINILOK QuickAnchor Plus (K030995) with respect to its indications for use, design, and function. Side-by-side performance testing demonstrates the substantial equivalence of the Flip Button Suture Anchor to the Arthrex Tak.