June 7, 2023

Osteonic Co., Ltd.
% Sanglok Lee
Manager
Wise Company Inc.
#507, #508, 166 Gasandigital 2-ro, Geumcheon-gu
Seoul, 08507
Korea, South

Re: K231322
Trade/Device Name: Fix2Lock(PEEK Self Punching)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 8, 2023
Received: May 8, 2023

Dear Sanglok Lee:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sara S. Thompson -S

For

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231322

Device Name
Fix2Lock (PEEK Self Punching)

Indications for Use *(Describe)*
Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure;
Orthopedic surgery for shoulders, knees, foot/ankle, hand/wrist and elbow.

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.

Date of Submission: 2023.06.07

01. Applicant

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02. Submission Correspondent

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03. Subject Device Identification

Trade Name: Fix2Lock (PEEK Self Punching)
Common Name: fastener, fixation, non-biodegradable, soft tissue
Classification Name: Smooth or threaded metallic bone fixation fastener
Classification Product Code: MBI
Panel: Orthopedic
Regulation Number: 21 CFR 888.3040
Device Class: II

04. Predicate Device

510(k) Number: K202763
Device Name: Fix2Lock (PEEK Self Punching)
Manufacturer: Osteonic Co., Ltd.

05. Reference Device

510(k) Number: K081511
Device Name: 2.0 PK Suture anchor T and 2.0 PK Suture anchor S
Manufacturer: Smith &Nephew, Inc.

510(k) Number: K202806
Device Name: Fix2Lock (Biocomposite medial, Biocomposite lateral, Biocombi Self Punching)
Manufacturer: Osteonic Co., Ltd.

06. Device Description

This product is used for orthopedic surgery, which soft tissue fix such as ligaments, tendons, and capsules to bone. The implant part is made of PEEK (polyether ether ketone, ASTM F2026) with non-absorbable suture and consists of Driver Handle and Driver Shaft for anchor insertion. This product is sterilized product and single use only.

07. Indication for use

Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure;
Orthopedic surgery for shoulders, knees, foot/ankle, hand/wrist and elbow.

08. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

▪ **Material**

- ASTM F2026: 2017 Standard specification for polyetheretherketone(PEEK) polymers for surgical implant applications
- ASTM F2848: 2017 Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
and Surgical Implants

▪ **Mechanical performance**

- ASTM F543: 2013 Standard specification and test methods for metallic medical bone screws

▪ **Sterilization, shelf life and packaging for sterile product**

- ISO 11135:2014, Sterilization of health-care products – Ethylene oxide – Requirements for the development validation and routine control of a sterilization and routine control of a sterilization process for medical devices
- ISO 11138-1:2006, Sterilization of health care products — Biological indicators — Part 1: General requirements
- ISO 11138-2:2009, Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 11140-1:2014, Sterilization of health care products — Chemical indicators — Part 1: General requirements
- ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods- Part 1: Estimation of population of microorganisms on products
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process
- ISO 11607-1:2006/AMD1:2014 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging system
- ISO 11607-2:2006/AMD1:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F88/F88M:2015 Standard test method for seal strength of flexible barrier materials.
- ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

▪ **Bacterial Endotoxin**

- USP <85> Bacterial Endotoxin Test
- USP <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests

09. Comparison of Technological Similarities and Differences

Table 1: Substantial Equivalence Comparison

Product Name	**Modified(Subject) Device** Fix2Lock (PEEK Self Punching), K231322	**Unmodified(Predicate) Device** Fix2Lock (PEEK Self Punching), K202763	**REFERENCE Device** 2.0 PK Suture anchor T and 2.0 PK Suture anchor S, K081511	**Equivalence Discussion**
Product code	MBI	MBI	MBI	Same
Regulatory class	Class II	Class II	Class II	Same
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040	Same
Intended use	Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure; Orthopedic surgery for shoulders, knees, foot/ankle, hand/wrist and elbow.	Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure; Orthopedic surgery for shoulders and knees.	The 2.0 PK Suture Anchor T and 2.0 PK Suture Anchor S is intended for use for reattachment of soft tissue to bone for the following indication: **Shoulder:** Capsular stabilization – Bankart repair, Anterior shoulder instability, Slap lesion repair, Capsular shift or capsulolabral reconstruction, Acromilavicular separation repairs, Deltoid repairs, Rotator cuff repairs and Biceps tenodesis **Foot/ankle:** Hallux valgus repairs, Medial or lateral instability repairs/reconstruction, Achilles tendon repairs/reconstruction, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/reconstruction and Bunionectomy. **Elbow, Wrist, and Hand:** Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, and Scapholunate ligament reconstruction. **Knee:** Extra-capsular repairs - Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament, Patellar realignment and tendon repairs – Vastus medialis obliquus advancement and Iliotibial band tenodesis.	Same

Operating Principles	This product is used for orthopedic surgery, which soft tissue fix such as ligaments, tendons, and capsules to bone.	This product is used for orthopedic surgery, which soft tissue fix such as ligaments, tendons, and capsules to bone.		Same
Material	PEEK anchor and non-absorbable sutures, needle	PEEK anchor and non-absorbable sutures.	PEEK. Non-absorbable suture, Stainless steel needle.	Similar
Structure	This product consists of an implanted anchor, non-absorbable suture, driver shaft and handle	This product consists of an implanted anchor, non-absorbable suture, driver shaft and handle	The 2.0 PK Suture Anchor T and the 2.0 PK Suture Anchor S consist of a non-absorbable suture anchor with attached non-absorbable suture(s) preassembles to a stainless steel insertion device, and is provided sterile, for single use only. Both anchor models achieve fixation via ribbed/threaded design characteristics that are consistent with the repair of soft tissue to bone.	Same
Product Size	2.3mm, 4.5mm, 4.8mm, 5.5mm type	4.5mm, 5.5mm type	2.03mm	Similar
Sterilization	Sterile (EtO sterilization)	Sterile (EtO sterilization)	Sterile	Same
Single Use/ Reuse	Single use	Single use	Single use	Same
Packaging	1 EA / BOX	1 EA / BOX		Same
Shelf life	3Years	5Years		Similar

The Product Size of subject device is similar with the predicate device and the safety was evaluated as the performance bench test.

Reference device had been added to demonstrate the equivalency with the marketed device. This is to resolve that the needles are not applied for unmodified device.

10. Substantially Equivalent Conclusion

Based on above, the subject device, Fix2Lock (PEEK Self Punching), is determined to be Substantially Equivalent (SE) to the Unmodified(Predicate) device, Fix2Lock (PEEK Self Punching) (K202763) ,in respect of safety and effectiveness.