December 3, 2024

Osteonic Co., Ltd.
% Lee Sanglok
Manager
Wise Company Inc.
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Seoul, 08502
Korea, South

Re: K243470
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: November 8, 2024
Received: November 8, 2024

Dear Lee Sanglok:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243470

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.

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

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Date of Submission: 2024.11.08

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: K231322
Device Name: Fix2Lock (PEEK Self Punching)
Manufacturer: Osteonic Co., Ltd.

05. Reference Device

510(k) Number: K233893
Device Name: AlphaVent Knotless SP PEEK Anchor
Manufacturer: Stryker Endoscopy

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: 2021 Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns and Surgical Implants

▪ **Mechanical performance**

- ASTM F543: 2017 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 Third edition 2017-03, Sterilization of health care products — Biological indicators — Part 1: General requirements
- ISO 11138-2:2017, 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 Third edition 2018-01 [Including AMD1:2021], Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
- ISO 11737-2 Third edition 2019-12, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11607-1 Second edition 2019-02, Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging system
- ISO 11607-2 Second edition 2019-02, 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-21 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
- ISO 11737-3:2023, Sterilization of health care products – Microbiological methods – Part 3: Bacterial endotoxin testing

09. Comparison of Technological Similarities and Differences

Table 1: Substantial Equivalence Comparison

Product Name	**Modified(Subject) Device** Fix2Lock (PEEK Self Punching),	**Unmodified(Predicate) Device** Fix2Lock (PEEK Self Punching), K231322	**REFERENCE Device** AlphaVent Knotless SP PEEK Anchor, K233893	**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, knees, foot/ankle, hand/wrist and elbow.	The AlphaVent Knotless SP PEEK Anchor is intended to be used for soft-tissue to bone fixation in the shoulder, foot and ankle, knee, hand and wrist, elbow, and hip in skeletally mature pediatric and adult patients. It is indicated for use in the following procedures: Shoulder: Rotator Cuff Repair, 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 Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair, Secondary or Adjunct Fixation for ACL/PCL Reconstruction or Repair, Meniscal Root Repair, MPFL Repair/Reconstruction Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Reconstruction, Lateral Epicondylitis Repair Hip: Capsular Repair, Acetabular Labral Repair, Gluteus Medius Repair, Proximal Hamstring Repair	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.	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	PEEK anchor and non-absorbable sutures, needle	PEEK anchor and non-absorbable sutures	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	This product consists of an implanted anchor, non-absorbable suture, driver shaft and handle	Same
Product Size	3.75mm ~ 6.5mm	2.3mm ~ 5.5mm	4.75mm, 5.5mm, 6.5mm	Similar
Sterilization	Sterile (EtO sterilization)	Sterile (EtO sterilization)	Sterile (EtO sterilization)	Same
Single Use/ Reuse	Single use	Single use	Single use	Same
Packaging	1 EA / BOX	1 EA / BOX	-	Same
Shelf life	3Years	3Years	-	Same

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 product size (6.5mm) is larger than the product size range of 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) (K231322) ,in respect of safety and effectiveness.