



May 31, 2023

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

Re: K231326

Trade/Device Name: Fix2Lock(Biocomposite medial, lateral, Biocombi Self Punching)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: April 1, 2023
Received: May 8, 2023

Dear Mr. 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

Yu-Chieh Chiu, Ph.D.
Acting 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

Indications for Use

510(k) Number (if known)

K231326

Device Name

Fix2Lock (Biocomposite medial, lateral, Biocombi Self Punching)

Indications for Use (Describe)

The Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure; shoulder, foot/ankle, knee, hand/wrist and elbow.

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, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

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

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament 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.

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The assigned 510(k) Number: K231326

Date of Submission: 2023.04.01

01. Applicant

OSTEONIC Co., Ltd.

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02. Submission Correspondent

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03. Subject Device Identification

Trade Name: Fix2Lock (Biocomposite medial, Biocomposite lateral, Biocombi Self Punching)

Common Name: Bioabsorbable bone anchor

Classification Name: fastener, fixation, non-biodegradable, soft tissue

Classification Product Code: MAI

Subsequent Product Code: MBI

Panel: Orthopedic

Regulation Number: 21 CFR 888.3030

Device Class: II

04. Predicate device

510(k) Number: K202806

Device Name: Fix2Lock (Biocomposite medial, Biocomposite lateral, Biocombi Self Punching)

Manufacturer: Osteonic Co., Ltd.

05. Reference device

510(k) Number: K192032

Device Name: Fixone Biocomposite Small Anchor

Manufacturer: AJU Pharm Co., Ltd..

06. Device Description

The Fix2Lock (Bioabsorbable bone anchor) is an absorbable bone fixation screw that fixes soft tissues such as ligament, tendon, and the articular capsules to bone, and is used in orthopedic surgery.

This product consists of an absorbable and/or non-absorbable anchor, a non-absorbable suture and driver shaft and handle.



07. Indication for use

The Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure; shoulder, foot/ankle, knee, hand/wrist and elbow.

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, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

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

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction



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	SUBJECT Device	Predicate Device	REFERENCE Device	Equivalence Discussion
Product code	MAI	Fix2Lock(Biocomposite medial, lateral, Biocombi Self Punching)(K202806)	Fixone Biocomposite Small Anchor (K192032)	Same
Regulatory class	Class II	Class II	Class II	Same
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	21 CFR 888.3030	Same
Intended use	The Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure; shoulder, foot/ankle, knee, hand/wrist and elbow. Shoulder: Rotator Cuff Repair,	The Fix2Lock is intended use for fixation of soft tissue to bone, using suture, in the following procedure; shoulder, foot/ankle, knee, hand/wrist and elbow.	The Fixone Biocomposite Small Anchor are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip.	Same



	<p>Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</p> <p>Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction</p> <p>Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</p> <p>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</p> <p>Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction</p>	<p>Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</p> <p>Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction</p> <p>Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</p> <p>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</p> <p>Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction</p>	<p>Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</p> <p>Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction</p> <p>Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</p> <p>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</p> <p>Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction</p> <p>Hip: Capsular repair, Acetabular Labral repair</p>	
Operating Principles	Bone fixation screw that ties soft tissues such as ligament, tendon, and the articular capsules to bone.	Bone fixation screw that ties soft tissues such as ligament, tendon, and the articular capsules to bone.	The Fixone Biocomposite Small Anchor is intended for reattaching soft tissue to bone with sutures.	Same
Material	<p>Anchor:</p> <ul style="list-style-type: none"> -Biocomposite medial, lateral: PLGA+β-TCP -Biocombi self punching: PLGA+β-TCP, PEEK <p>Suture: UHMWPE</p>	<p>Anchor:</p> <ul style="list-style-type: none"> -Biocomposite medial, lateral: PLGA+β-TCP -Biocombi self punching: PLGA+β-TCP, PEEK <p>Suture: UHMWPE</p>	PLGA+ β -TCP	Same
Structure	This product consists of an absorbable and/or non-absorbable anchor, a non-absorbable suture, needle and driver shaft and handle.	This product consists of an absorbable and/or non-absorbable anchor, a non-	Driver, Anchor, Suture and needle	Same



		absorbable suture and driver shaft and handle.		
Product Size	Anchor diameter: Ø 2.6 to 4.8 mm Anchor length: 10.0 to 16.0mm	Anchor diameter: Ø 2.6 to 6.5 mm Anchor length: 10.0 to 20.8mm	Anchor diameter : Ø 3.0mm Length : 11.9mm	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	5Years	-	Same

The Product Size of subject device is similar with the predicate device. It is not exactly same but the size of subject device is within the range of unmodified device and the safety was evaluated as the performance bench test.

10. Substantially Equivalent Conclusion

Based on above, the subject device, Fix2Lock (Biocomposite medial, lateral, Biocombi Self punching), is determined to be Substantially Equivalent (SE) to the predicate device(Unmodified device), Fix2Lock(Biocomposite medial, lateral, Biocombi Self punching), (K202806) in respect of safety and effectiveness.