June 17, 2021

Osteonic Co., Ltd.
% Sanglok Lee
Manager
Wise Company Inc.
#303, 142, Gasan digital 1-ro
Geumcheon-gu, Seoul 08507
Korea, Republic of

Re: K202806
Trade/Device Name: Fix2Lock (Biocomposite medial, Biocomposite lateral, Biocombi Self Punching)
Regulation Number: 21 CFR 888.3030
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: September 22, 2020
Received: September 23, 2020

Dear Sandlok 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,

for

Laura C. Rose, 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)*
K202806

Device Name
Fix2Lock(Biocomposite medial, Biocomposite 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: K202806

01. Date of Submission: 2020.09.17

02. Applicant

Dakyung Ham
OSTEONIC Co., Ltd.
303Ho, 405Ho, 505-2Ho, 505-3Ho, 902Ho, 1004Ho, 1201Ho, 1202Ho, 1206Ho, 38 Digital-ro 29-gil, Guro-gu, Seoul, Korea, 102Ho, 103Ho, 24, Digital-ro 27-gil, Guro-gu, Seoul, Korea
TEL: +82-2-6902-8456
FAX: +82-2-6902-8401
Email: dakham@osteonic.com

03. Submission Correspondent

Sanglok, Lee
Wise COMPANY Inc.
#303, 142, Gasan digital 1-ro, Geumcheon-gu, Seoul, Korea
TEL: +82 70 8812 3619 / +82 2 831 3615
FAX: +82 50 4031 3619
Email: info@wisecompany.org

04. 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

05. 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

06. Predicate devices

Predicate device
510(k) Number: K192032
Device Name: Fixone Biocomposite Small anchor
Manufacturer: AJU Pharm Co., Ltd.

Reference device
510(k) Number: K192484
Device Name: Fixone Biocomposite anchor
Manufacturer: AJU Pharm Co., Ltd.

510(k) Number: K181774
Device Name: Force Fiber ® Suture
Manufacturer: Teleflex Medical Incorporated

510(k) Number: K172016
Device Name: Force Fiber Fusion™ Suture
Manufacturer: Teleflex Medical Incorporated

07. 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.

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

▪ **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. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	**SUBJECT Device**	**PREDICATE Device** Fixone Biocomposite Small anchor (K192032)	**REFERENCE Device 1** Fixone Biocomposite anchor (K192484)	**Equivalence Discussion**
Product code	MAI	MAI, MBI	MAI	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, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral	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. Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clabicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral	The Fixone Biocomposite Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee and elbow in the following procedures: Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation	Similar

	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	Reconstruction Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Midfoot 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 Hip: Capsular repair, Acetabular Labral repair	Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction; Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair; Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, lliotibial Band Tenodesis; Elbow: Biceps Tendon Reattachment, UInar or Radial Collateral Ligament Reconstruction.	
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.	Bone fixation screw that ties soft tissues such as ligament, tendon, and the articular capsules to bone.	Same
Material	Anchor: -Biocomposite medial, lateral: PLGA+ β -TCP -Biocombi self punching: PLGA+ β -TCP, PEEK Suture: UHMWPE	Anchor: PLGA+ β -TCP Suture: UHMWPE	Anchor: PLGA+ β -TCP Suture: UHMWPE	Similar
Structure	This product consists of an absorbable and/or non-absorbable anchor, a non-absorbable suture and driver shaft and handle.	This product consists of an absorbable anchor, a non-absorbable suture and driver shaft and handle.	This product consists of an absorbable anchor, a non-absorbable suture and driver shaft and handle.	Similar
Product Size	Anchor diameter: Ø 2.6 to 6.5 mm Anchor length: 10.0 to 20.8mm	Anchor diameter: Ø 3.0mm Anchor length: 11.9mm	Anchor diameter: Ø 3.0 to 6.5 mm Anchor length: 11.9 to 16.8mm	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	1 EA / BOX	Same
Shelf -life	5Years	5Years	5Years	Same

Based on above, the subject device, Fix2Lock **(Biocomposite medial, Biocomposite lateral, Biocombi Self Punching)**, is determined to be Substantially Equivalent **(**SE**)** to the predicate devices, Fixone Biocomposite Small anchor (K192032) in respect of safety and effectiveness.