August 27, 2021

OSTEONIC Co., Ltd.
% Sanglok Lee
Manager
WISE COMPANY Inc.
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Geumcheon-gu, Seoul 08507
South Korea

Re: K210122
Trade/Device Name: Sterile Bioabsorbable Bone Screw (Biocomposite ACL Screw)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: July 20, 2021
Received: July 22, 2021

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,

Laura C. Rose -S

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
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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)*
K210122

Device Name
Sterile bioabsorbable bone screw (Biocomposite ACL screw)

Indications for Use *(Describe)*
Sterile bioabsorbable bone screw (Biocomposite ACL screw) is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used in orthopedic surgery(Cruciate ligament reconstruction procedures).

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: K210122

1. 510(k) Summary Date: 15.01.2021

2. Applicant

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4. Subject Device Identification

1) Trade Name: Sterile bioabsorbable bone screw (Biocomposite ACL screw)
2) Common Name: Sterile bioabsorbable bone screw (Biocomposite ACL screw)
3) Classification Name: fastener, fixation, biodegradable, soft tissue
4) Product Code: MAI
5) Panel: Orthopedic
6) Regulation Number: 21 CFR 888.3030
7) Device Class: II

5. Indication for use

Sterile bioabsorbable bone screw (Biocomposite ACL screw) is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used in orthopedic surgery(Cruciate ligament reconstruction procedures).

6. Predicate devices

Predicate device
1) 510(k) Number: K143660
2) Device Name: Milagro/Milagro Advance Interference Screw
3) Manufacturer: DePuy Mitek, Inc.

Reference device
1) 510(k) Number: K103831
2) Device Name: Milagro Interference screw
3) Manufacturer: DePuy Mitek, Inc.

Reference device
1) 510(k) Number: K202806
2) Device Name: Fix2Lock (Biocomposite medial, Biocomposite lateral, Biocombi SelfPunching)
3) Manufacturer: Osteonic Co., Ltd.

7. Device Description

The Sterile bioabsorbable bone screw (Biocomposite ACL screw) 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.

The implanted screw is made of poly(L-lactide-co-glycolide), PLGA and tri-calciumphosphate(β-TCP). Poly(L-lactide-co-glycolide), PLGA is gradually decomposed in vivo by hydrolysis and eventually excreted in carbon dioxide and water. Tri-calciumphosphate(β-TCP) is gradually degraded in vivo by hydrolysis and eventually re-used as a calcium source.

Sterile bioabsorbable bone screw (Biocomposite ACL screw) is supplied EO gas sterile state and it is packed in Aluminum Pouch.

8. Non-Clinical Test Conclusion

1) General Information

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The following standards were used to support substantial equivalence:

- **Mechanical Performance**
  - ASTM F2502:17 Standard Specification and test methods for absorbable plates and screws for internal fixation implants
  - ISO 13781:2017 Implants for surgery – Homopolymers, copolymers and blends on poly(lactide) – In vitro degradation testing
- **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

2) Summary of Biocompatibility

Sterile bioabsorbable bone screw (Biocomposite ACL screw) has been evaluated for biocompatibility according to ISO 10993.

3) Summary of Performance

All specimens selected (worst-case) to verify the performance of the screw met the test criteria established based on literatures and comparison with the predicate device. Therefore, the performance of the entire model was proven.

No.	Test Article	Test Method	Result
1	Axial Pullout Strength	Test referring ASTM F2502-A3.Test Method for Axial Pullout of Absorbable Bone Screws. After fully inserting the screw into the artificial bone (20PCF), Apply tensile load to the specimen at a rate 5mm/min until the screw fails or releases from the block. Measure the maximum load.	PASS
2	Torsional Yield Strength	Test referring ASTM F2502-A1.Test Method for Determining the Torsion Properties of Absorbable Bone Screws. After placing the specimen in the holding device, Rotate the screw in inserting direction at a rate of 1 revolution/min. Torsional yield strength is determined by an off-set method (2 degree off-set) on the torque versus rotation angle curve measured in the test.	PASS
3	Driving Torque	Test referring ASTM F2502-A2.Test Method for Driving Torque of Absorbable Bone Screws. Make a hole in the fixed artificial bone (20PCF) using an instrument compatible with the product. Measure the maximum strength when the screw is inserted 4 revolutions at a rate of 5 revolutions per minute. * Inserting load (axial load) = 1.14kgf	PASS
4	Degradation testing	Mechanical performance assessed after degradation according to ISO 13781	PASS
5	Fatigue	After fully inserting the screw with the tendon into the fixed artificial bone (20PCF), a fatigue tensile load of 70 to 220N	PASS

		on the tendon is repeated 1000 cycles at 1 Hz.	

9. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	**SUBJECT Device**	**PREDICATE Device** Milagro/Milagro Advance Interference Screw (K143660)	**REFERENCE Device 1** Milagro Interference screw (K103831)	**Equivalence Discussion**
Product code	MAI	MAI	MAI, HWC	Same
Regulatory class	Class II	Class II	Class II	Same
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	21 CFR 888.3040	Same
Intended Use	Sterile bioabsorbable bone screw (Biocomposite ACL screw) is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used in orthopedic surgery(Cruciate ligament reconstruction procedures).	Milagro Interference screw(5x12,6x12,7x15,8x15) The MILAGRO BR Interference screws are designed to attach soft tissues to bone in Ortohpedic surgical procedures for the following indications: Shoulder : Proximal Biceps Tenodesis, Acromio-Clavicular Repair Elbow: Distal Biceps Tenodesis, Ulnar Collateral Ligament Repair Knee: Collateral Ligament Repair, Medial Patellofemoral Ligament Reconstruction (patella fixation) Milagro Acvance Interference screw(7x23,8x23,9x23) The MILAGRO ADVANCE Interference screw is intended for attachment of soft tissue grafts or bone-tendon-bone grafts to the tibia and/or femer during cruciate ligament reconstruction procedures. Additionally, the 7, 8 and 9mm x 23mm screws are indicated for : medial and lateral collateral ligament repair, medial patellofemoral ligament reconstruction(femer fixation) of the knee, proximal bicep tenodesis in the shoulder and distal bicep tenodesis in the elbow.	Knee : - Attachment of a bone-tendon-bone(BTB)graft to the tibia and/or femur during cruciate ligament reconstruction procedure. - Attachment of a soft tissue (ST)graft to the tibia and/or femur during cruciate ligament reconstruction procedures. - Medial and lateral collateral ligament repair Shoulder : Proximal bicep tenodesis Elbow : Distal bicep tenodesis	Same
Operating Principles	Sterile bioabsorbable bone screw (Biocomposite ACL screw) is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and	Milagro/Milagro Advance Interference Screw is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used	Milagro Interference screw is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used in orthopedic surgery(Cruciate	Same

	is used in orthopedic surgery(Cruciate ligament reconstruction procedures).	in orthopedic surgery(Cruciate ligament reconstruction procedures).	ligament reconstruction procedures).	
Material	PLGA + ß-TCP	Composite of ß-TCP and PLGA copolymer	Absorbable Poly(lactide -co-glycolide) polymer and Tricalcium Phosphate(TCP)	Same
Product Size	Ø7.0 x (25,30) mm Ø8.0 x (23,25,28,30) mm Ø9.0 x (23,25,28,30) mm Ø10.0 x (23,25,28,30) mm	Ø5.0 x 12 mm Ø6.0 x 12 mm Ø7.0 x (15,23) mm Ø8.0 x (15,23) mm Ø9.0 x 23 mm	Ø5.0 x (23,30) mm Ø6.0 x (23,30) mm Ø7.0 x (23,30) mm Ø8.0 x (23,30) mm Ø9.0 x (23,30,35) mm Ø10.0 x (23,30,35) mm Ø11.0 x (30,35) mm Ø12.0 x (30,35) mm	Similar
Sterilization	Sterile (EO gas sterilization)	Sterile (EO gas sterilization)	Sterile (EO gas sterilization)	Same
Single Use/ Reuse	Single use	Single use	Single use	Same
Packaging	1 EA / BOX	1 EA / BOX	1 EA / BOX	Same

Based on above, the subject device, **Sterile absorbable bone screw (Biocomposite ACL screw),** is determined to be Substantially Equivalent **(**SE**)** to the predicate devices, Milagro/Milagro Advance Interference Screw (K143660) in respect of safety and effectiveness.