December 26, 2023

OSTEONIC Co., Ltd.
℅ Sanglok Lee
Manager
Wise Company Inc.
#1107, #1108, 204 Gasandigital 1-ro, Geumcheon-gu
Seoul, 08502
Korea, South

Re: K233659
Trade/Device Name: Suture Wing
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 17, 2023
Received: November 15, 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 (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.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233659

Device Name

Suture Wing

Indications for Use *(Describe)*

Suture wing is intended for fixation of soft tissue to bone, using suture, in orthopedic surgery.

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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The assigned 510(k) Number : K233659

Date of Submission: 2023.10.17

01. Applicant

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02. Submission Correspondent

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03. Subject Device Identification

Trade Name: Suture Wing
Common Name: Sterile bone anchor-all suture
Classification Name: fastener, fixation, non-biodegradable, soft tissue
Classification Product Code: MBI
Panel: Orthopedic
Regulation Number: 21 CFR 888.3040
Device Class: II

04. Predicate device

510(k) Number: K202663
Device Name: Suture Wing
Manufacturer: Osteonic Co., Ltd.

05. Reference device

510(k) Number: K231326
Device Name: Fix2Lock (Biocomposite medial, Biocomposite lateral, Biocombi Self Punching)
Manufacturer: OSTEONIC Co., Ltd.

510(k) Number: K110879
Device Name: JuggerKnotTM Mini Soft Anchors
Manufacturer: BIOMET SPORTS MEDICINE

06. Device Description

This product is used for orthopedic surgery, which soft tissue fix such as ligaments, tendons, and capsules to bone. The anchor and sutures is made of non-absorbable and consists of Driver Handle and Driver Shaft for anchor insertion. This product is sterilized product and single use only.
Sterile bone anchor-all suture is supplied EO gas sterile state and it was packed in tyvek and PE film.

07. Indication for use

Suture wing is intended for fixation of soft tissue to bone, using suture, in orthopedic surgery.

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 F2848: 2021 Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
- ASTM F2063: 2018 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants

▪ **Mechanical performance**

- ASTM F543: 2017 Standard specification and test methods for metallic medical bone screws
- ASTM F1839: 2008 (Reapproved 2016), Standard specification for rigid polyurethane foam for use as a standard material for testing orthopaedic devices and instruments

▪ **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 11138-1:2017, 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 11737-2:2019 Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process
- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging system
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980:2021 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-NF M98830_02_01 <85> Bacterial Endotoxins Test
- USP-NF M98910_01_01 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests

▪ **Material mediated pyrogenicity**

- USP <151> Pyrogenicity Test
- ISO 10993-11: Tests for systemic toxicity

▪ **Insertion test**

- FDA guidance : Bone Anchors – Premarket notification (510(K)) Submissions
- ASTM F1839: 2008 (Reapproved 2016), Standard specification for rigid polyurethane foam for use as a standard material for testing orthopaedic devices and instruments

09. Comparison of Technological Similarities and Differences

Table 1: Substantial Equivalence Comparison

Product Name	**Modified(Subject) Device** Suture wing, K233659	**Unmodified(Predicate) Device** Suture wing, K202663	**Reference Device** JuggerKnot™ Mini Soft Anchors, K110879	**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	Suture wing is intended for fixation of soft tissue to bone, using suture, in orthopedic surgery.	Suture wing is intended for fixation of soft tissue to bone, using suture, in orthopedic surgery.	The JuggerKnot™ Mini Soft Anchors are intended to be used for tissue to bone fixation with indications for use In: Shoulder: Bankart repair Foot and Ankle: Midfoot Reconstruction, Hallux valgus reconstruction Hand and Wrist: Ulnar or lateral collateral ligament reconstruction, Repair/reconstruction of collateral ligaments, flexor and extensor tendon at the PIP(proximal interphalangeal, DIP (Distal Interphalangeal), and MCP(Metacarpal interphalangeal) joints for all digits, Scapholunate ligament reconstruction.	Same
Operating Principles	Bone fixation anchor that ties soft tissues such as ligament, tendon, and the articular capsules to bone.	Bone fixation anchor that ties soft tissues such as ligament, tendon, and the articular capsules to bone.	The anchors are intended for use in soft tissue fixation by bunching against bone when deployed.	Same
Material	Anchor and suture: UHMWPE Needle	Anchor and suture: UHMWPE	Anchor and suture: UHMWPE Needle	Similar
Structure	This product consists of a non-absorbable all suture and driver shaft and handle and needle.	This product consists of a non-absorbable all suture and driver shaft and handle.	Driver, Anchor, Suture and needle	Same
Product Size	1.5mm / 1.7mm / 2.8mm	1.7mm/ 2.8mm	1.0mm	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	-	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, Suture Wing, is determined to be Substantially Equivalent (SE) to the Unmodified(Predicate) device, Suture Wing(K202663), in respect of safety and effectiveness.