November 25, 2020

Osteonic Co., Ltd.
% Sanglok Lee
Manager
WISE COMPANY Inc.
#507-508, 166 Gasan digital 2-ro
Geumcheon-gu, Seoul, Republic of Korea 08503

Re: K202883
Trade/Device Name: Sterile bone screw (PEEK ACL screw)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 24, 2020
Received: September 28, 2020

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, 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

OSTEONIC
1206Ho, 38, Digital-ro 29-gil, Guro-gu, Seoul, Korea
Tel: +82(2)-6902-8400 Fax: +82(2)-6902-8401 Home page: http://www.osteonic.com

The assigned 510(k) Number: K202883

1. 510(k) Summary Date: 11. 23. 2020

2. Applicant

Sung-moo Hwang
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: +82-2-6902-8426
FAX: +82-2-6902-8401
Email: sungmhwang@osteonic.com

3. Submission Correspondent

Sang-lok, 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

4. Subject Device Identification

1) Trade Name: Sterile bone screw (PEEK ACL screw)
2) Common Name: Sterile bone screw (PEEK ACL screw)
3) Classification Name: fastener, fixation, non-biodegradable, soft tissue
4) Product Code: MBI
5) Panel: Orthopedic
6) Regulation Number: 21 CFR 888.3040
7) Device Class: II

5. Indication for use

The Sterile bone screw (PEEK 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.

Knee
- ACL repairs
- PCL repairs
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament

OSTEONIC
1206Ho, 38, Digital-ro 29-gil, Guro-gu, Seoul, Korea
Tel: +82(2)-6902-8400 Fax: +82(2)-6902-8401 Home page: http://www.osteonic.com

– Posterior oblique ligament
• Patellar realignment and tendon repairs
– Vastus medialis obliquus advancement
• Iliotibial band tenodesis

6. Predicate devices

1) 510(k) Number: K083635
2) Device Name: Biosure PK Interference Screw
3) Manufacturer: Smith&Nephew PK Interference Screw

7. Device Description

The Sterile bone screw (PEEK ACL screw) is a 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 PEEK (poly-ether-ether-ketone, ASTM F2026).

The Sterile bone screw (PEEK ACL screw) is supplied gamma irradiation sterile state and it is packed in Tyvek 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 test results demonstrated that the subject device complies with the following standards:

▪ **Material**
- ASTM F2026:2017, Standard Specification for Poly-ether-ether-ketone(PEEK)Polymer for Surgical Implant Applications

▪ **Mechanical Performance**
- ASTM F543:17 Standard Specification and test method for metallic bone screws

▪ **Sterilization, Shelf-life and Packaging for Sterile Product**
- ISO 11138-1:2006, Sterilization of health care products — Biological indicators — Part 1: General requirements
- ISO 11140-1:2014, Sterilization of health care products — Chemical indicators — Part 1: General requirements
- ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11137-3:2017, Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- 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

OSTEONIC
1206Ho, 38, Digital-ro 29-gil, Guro-gu, Seoul, Korea
Tel: +82(2)-6902-8400 Fax: +82(2)-6902-8401 Home page: http://www.osteonic.com

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

The Sterile bone screw (PEEK 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. Therefore, the performance of the entire model was proven.

No.	Test Article		Test Method	Result
1	Axial Pullout Strength		ASTM F543-A3.Test Method for Determining the Axial Pullout Strength of Medical Bone Screws.	PASS
2	Torsional Yield Strength		ASTM F543-A1.Test Method for Determining the Torsional Properties of Metallic Bone Screws.	PASS
3	Driving Torque	Insertion	ASTM F543-A2.Test Method for Driving Torque of Medical Bone Screws.	PASS
		Removal		
4	Fatigue		After fully inserting the screw with the tendon into the fixed artificial bone (20PCF), a fatigue tensile load of 70 to 220N on the tendon is repeated 1000 cycles at 1 Hz.	PASS

9. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	SUBJECT Device	PREDICATE Device Biosure PK Interference Screw (K083635)	Equivalence Discussion
Product code	MBI	MBI	Same
Regulatory class	Class II	Class II	Same
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Same
Intended Use	The Sterile bone screw (PEEK 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.	The BIOSURE PK Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 25 mm or less are also	Same

OSTEONIC
1206Ho, 38, Digital-ro 29-gil, Guro-gu, Seoul, Korea
Tel: +82(2)-6902-8400 Fax: +82(2)-6902-8401 Home page: http://www.osteonic.com

	Knee • ACL repairs • PCL repairs • Extra-capsular repairs – Medial collateral ligament – Lateral collateral ligament – Posterior oblique ligament • Patellar realignment and tendon repairs – Vastus medialis obliquus advancement • Iliotibial band tenodesis	intended for use in the following procedures: **Knee** • ACL repairs • PCL repairs • Extra-capsular repairs – Medial collateral ligament – Lateral collateral ligament – Posterior oblique ligament • Patellar realignment and tendon repairs – Vastus medialis obliquus advancement • Iliotibial band tenodesis **Shoulder** • Acromioclavicular separation repairs • Biceps tenodesis **Foot and Ankle** • Medial or lateral instability repairs/ reconstructions • Achilles tendon repairs/reconstructions • Metatarsal ligament/tendon repairs/ reconstructions • Flexor hullucis longus (FHL) • Tendon transfers **Elbow, Wrist, and Hand** • Biceps tendon reattachment • Ulnar or radial collateral ligament reconstructions • Lateral epicondylitis repair • Scapholunate ligament reconstruction • Tendon transfers • Carpomedicarpal joint arthroplasty	
Operating Principles	The Sterile bone screw (PEEK 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.	The Biosure PK 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.	Same
Material	PEEK 100% (Optima PEEK)	PEEK 100% (Optima PEEK)	Same
Product Size	Ø 7.0 x (25,30) mm Ø 8.0 x (25,30) mm Ø 9.0 x (25,30) mm Ø 10.0 x (25,30) mm	Ø 6.0 x (20,25,25(R)) mm Ø 7.0 x (20,25,25(R),30) mm Ø 8.0 x (20,25,25(R),30,35) mm Ø 9.0 x (20,25,30,35) mm Ø 10.0 x (20,25,30,35) mm Ø 11.0 x (25,30,35) mm Ø 12.0 x 35 mm	Similar
Sterilization	Sterile (Gamma sterilization)	Sterile (Gamma sterilization)	Same
Single Use/ Reuse	Single use	Single use	Same
Packaging	1 EA / BOX	1 EA / BOX	Same
Shelf -life	5Years	5Years	Same

Based on above, the subject device, **Sterile bone screw (PEEK ACL screw),** is determined to be Substantially Equivalent **(**SE**)** to the predicate devices, Biosure PK Interference Screw (K083635) in respect of safety and effectiveness.