October 15, 2021

Osteonic Co., Ltd.
Lee Jisun
Manager
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Guro-gu, Seoul 08381
REPUBLIC OF KOREA

Re: K211992
Trade/Device Name: Ortho MI System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: July 14, 2021
Received: July 19, 2021

Dear Lee Jisun:

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 Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K211992

Device Name
ORTHO MI SYSTEM

Indications for Use *(Describe)*
The ORTHO MI SYSTEM is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. It is intended for single use only.

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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510(k) Summary

The assigned 510(k) Number: K211992

01. Date of Submission: 2021.10.15

02. Applicant

LEE JISUN
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03. Submission Correspondent

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04. Subject Device Identification

Trade Name: ORTHO MI SYSTEM
Common Name: Non sterile, sterile orthodontic anchor screw
Classification Name: Implant, Endosseous, Orthodontic
Product Code: OAT
Panel: Dental
Regulation Number: 21 CFR 872.3640
Device Class: II

05. Indication for use

The ORTHO MI SYSTEM is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. It is intended for single use only.

06. Predicate devices

Predicate device
510(k) Number: K103105
Device Name: Orthodontic screw
Manufacturer: OSSTEM Implant Co., Ltd.

Reference device
510(k) Number: K161335
Device Name: Dual Top Screw System
Manufacturer: Jeil Medical Corporation

07. Device Description

The ORTHO MI SYSTEM is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. It is intended for single use only.

The screw diameters and lengths vary as shown below. It is made of a machined piece of Ti-6Al-4V ELI titanium alloy (ASTM F 136-13).

Structure (head type)	Thread diameter and Length	Remark
Double head Button head Wing Slot	- Ø1.4mm, 6.0/8.0mm - Ø1.6mm, 6.0/8.0/10.0mm - Ø1.8mm, 6.0/8.0/10.0mm - Ø2.0mm, 6.0/8.0/10.0/12.0mm	Exceptionally S5T (Double head) and S5R (Slot) are Ø1.8mm, 10.0 to 16.0mm per 1.0mm.

These size combinations are the same across all model types (Double Head, Button head, Wing, Slot) with exception case.

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:

▪ **Mechanical performance**

- ISO 19023: 2018 Dentistry - Orthodontic anchor screws
- ASTM F543: 2013 Standard specification and test methods for metallic medical bone screws

▪ **Sterilization, shelf-life and packaging for sterile product**

- ISO11137-1:2006/Amd.2:2018 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]
- ISO11137-2:2013Sterilization of health care products -Requirements for validation and routine control – Radiation – Part 2: Establishing the sterilization dose
- ISO11137-3:2017Sterilization of health care products -Requirements for validation and routine control – Radiation – Part 3: Guidance on dosimetric aspects
- ISO11737-1:2018 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 F1140/F1140M:2013 Standard test methods for internal pressurization failure resistance of unrestrained packages for medical applications
- ASTM F2096:2011 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D882:2012 Standard test method for tensile properties of thin plastic sheeting.
- ASTM F1886/F1886M:2016 Standard Test Method for Determining Integrity of Seals for flexible packaging by visual inspection

▪ **Sterilization for non-sterile product**

- ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 17665-1:2006 Sterilization of health care products -- moist heat -- part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices.

- ISO TS 17665-2:2009 Sterilization of health care products - moist heat - part 2: guidance on the application of iso 17665-1.
- ISO 11138-1:2017 Sterilization of health care products - biological indicators - part 1: general requirements

▪ **Biological safety assessment**

Biological assessment has been performed according to ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and to the FDA Guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff", for the subject devices.

09. Clinical Test Summary

No clinical data were necessary for the demonstration of substantial equivalence.

10. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	**SUBJECT Device** ORTHO MI SYTEM (K211992)	**PREDICATE Device** Orthodontic screw (K103105)	**REFERENCE Device** Dual Top Screw System **(**K161335**)**
Manufacturer	OSTEONIC Co., Ltd.	OSSTEM Implant Co., Ltd.	Jeil Medical Corporation
Product code	OAT	OAT	OAT
Regulatory class	Class II	Class II	Class II
Regulation Number	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Indication for use	The ORTHO MI SYSTEM is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. It is intended for single use only.	The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.	The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.
Operating Principles	Orthodontic anchorage screw is inserted into jaw and palatal to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	Orthodontic anchorage screw is inserted into jaw and palatal to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	Orthodontic anchorage screw is inserted into jaw and palatal to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.
Material	Titanium alloy (Ti6Al4V)-ASTM F136	Titanium alloy (Ti6Al4V)-ASTM F136	Titanium alloy (Ti6Al4V)-ASTM F136
Form	Orthodontic Anchorage Screw	Orthodontic Anchorage Screw	Orthodontic Anchorage Screw
Structure	Double head Button head Wing Slot	Through hole: wire hole Simple head: no hole Tapered body	Double head Button head Wing Slot
Color	Silver	Silver	Silver

Product Size	Diameter: Ø1.4 to 2.0 Thread Length: 6.0mm to 16.0mm (included an unthreaded length under head) Diameter by thread length Ø1.4mm- 6.0mm to 8.0mm Ø1.6mm and Ø1.8mm- 6.0mm to 10.0mm Ø2.0mm- 6.0mm to 12.0mm Exception -S5T and S5R-: Ø1.8mm- 10.0mm to 16.0mm)	Diameter: Ø1.4 to 1.8 Thread Length: 6mm to 10mm	Diameter: Ø1.3 to 2.5 Thread Length: 5mm to 16mm (included an unthreaded length under head)
Sterilization	Non sterile (user sterilization) or Sterile (Radiation)	Sterile (Radiation)	Non sterile (user sterilization) or Sterile (Radiation)
Single Use/ Reuse	Single use	Single use	Single use
Packaging	1 or 10ea / Pack	1ea / Pack	-
Shelf -life	Non sterile product- N/A, Sterile product-3Years	5Years	Non sterile product- N/A, Sterile product-5Years

There are slightly different diameters and thread length between the subject and predicate device. The reference device was added to support the difference diameters and lengths of the subject. The size of the subject device is included in the range of the predicate and reference device. The result of the comparative bench testing in line with ISO 19023 demonstrate that all screws are similar performance with predicate and/or reference device.
The technological characteristics of subject device is same materials and has similar structures and has similar dimension as the predicate and/or reference device.
The Indication for use of subject device is same as the predicate device.

Based on above, the subject device, **ORTHO MI SYSTEM**, is determined to be Substantially Equivalent **(**SE**)** to the predicate devices and reference device, Orthodontic screw (K103105) and Dual Top Screw System **(**K161335**)**.