August 13, 2025

Osstem Implant Co., Ltd.
% Mateusz Leszczak
Regulatory Affairs Manager
Hiossen Inc.
85 Ben Fariless Dr.
Fariless Hills, Pennsylvania 19030

Re: K251569
Trade/Device Name: Bone Screw
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: April 24, 2025
Received: May 22, 2025

Dear Mateusz Leszczak:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Sherrill Lathrop Blitzer

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251569

Device Name

Bone Screw

Indications for Use *(Describe)*

Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K251569

Date: July 30, 2025

1. Company and Correspondent making the submission

- Submitter's Name : Osstem Implant Co., Ltd.
- Address : 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
- Contact : Ms. Seungju Kang
- Phone : +82-70-4871-0203
- Correspondent's Name : Hiossen Inc.
- Address : 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact : Mr. Mateusz Leszczak
- Phone : +1-201-266-0657

2. Proposed Device

- Trade or (Proprietary) Name : Bone Screw
- Classification Name : Intraosseous fixation screw or wire
- Regulation Number : 21 CFR 872.4880
- Device Classification : Class II
- Classification Product Code : DZL

3. Predicated Device(s)

Primary Predicate		
K182881	Osstem Implant Co., Ltd.	Bone Screw, Bone Tack
Reference Device		
K201210	Hager & Meisinger GmbH	Micro Screw System, Micro Screw System Basic
K172354	Osstem Implant Co., Ltd.	OssBuilder System

4. Description

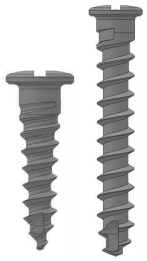
Bone Screw is using as anchor to fix the bone plate, membrane that cover bone material or block bone for bone regeneration or remodeling. Ø1.2 diameter screw is for fixing non-resorbable membrane or non-resorbable titanium membrane (Osstem OssBuilder OB2 and OB3), cleared in K172354.

The specifications of the proposed device are as follow;

Device	Content	
Bone Screw	Diameter (mm)	Ø1.2
	Length (mm)	3.0, 4.0, 5.0

5. Substantial Equivalence Matrix

	Subject Device	Primary Predicate	Reference Device	Comparison
Device Name	Bone Screw	Bone Screw	Micro Screw System	-
510(k) Number	K251569	K182881	K201210	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Hager & Meisinger GmbH	Same
Product Code	DZL	DZL	DZL	Same

Design				Same
Indication for Use	Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity.	Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. Bone Tack is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.	The Micro Screw System, Micro Screw System Basic are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field. Note: Micro Screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.	Same applies to Bone Screw
Thread Diameter (Ø)	1.2	1.4, 1.95	1.0, 1.2	Same with reference device
Length (mm)	3/4/5	3/4/5/6/8/10/12/14/16	4/6/8/10/12/14	Same
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Stainless steel (1.4441/UNS S 31673)	Same
Surface treatment	Machined	Machined	Smooth surface	Same
Drill head geometry				Same
Sterilization	Gamma Irradiation, Sterile	Gamma Irradiation, Sterile	Non-sterile	Same
Shelf life	8 years	8 years	N/A	Same
Substantial Equivalence	**Similarities** Proposed Bone Screw has same material, indications for use, manufacturer, manufacturing process, range of length, etc. with primary predicate. Also, it has same thread diameter with reference device, K201210. **Differences** The subject device has smaller thread diameter compared to that of the primary predicate. The additional thread diameter ⌀ 1.2 is same to the reference device, and we conducted mechanical comparison test with the reference device for performance. As a result, we confirmed that the subject device has equivalence performance with reference device. Therefore, the subject device do not raise new safety and			

	effectiveness concerns. ∴ Proposed Bone Screw and the predicate devices have common in function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Bone Screw is substantially equivalent to the predicate device.

6. Indications for Use

Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity.

7. Summary of Non-Clinical Performance Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence.

Biocompatibility Evaluation

The biocompatibility testing was considered followed 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,"* and the ISO 10993 suite of standards. The biocompatibility for the proposed device was found to be substantially equivalent to the predicate devices as a result.

Performance Test

Several performance tests were conducted between the subject device and predicate device according to ASTM F543-17 to demonstrate substantially equivalence.

- Driving Torque ("to measure the torque required to drive a bone screw into a standard material")
- Axial Pullout Strength ("to measure the axial tensile force required to fail or remove a bone screw from a defined material")
-Torsional Strength ("to measure the torsional yield strength, maximum torque, and breaking angle of the bone screw under standard conditions")

Sterilization Validation and Shelf-life

Validation of the gamma irradiation process was previously conducted for the predicated device K182881. The manufacturing or sterilization processes of predicates and the change in dimensions of the subject devices do not create the new worst-case scenario for sterilization; therefore, additional validation is not required.

The shelf-life of the subject device is supported by packaging validation data previously submitted under predicate device clearance K182881. The predicate submission established an 8-year shelf-life for devices utilizing the same materials, packaging configuration, gamma sterilization method, and comparable size ranges. As the subject device shares these key attributes, the data from K182881 is considered applicable and may be leveraged to support the shelf-life of the subject device.

MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the Subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

8. Summary of Clinical Testing

No clinical studies are submitted.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Osstem Implant Co., Ltd. concludes that the Bone Screw is substantially equivalent to the predicated device as herein.