Ossvis Co., Ltd.
Woojin Lee
Regulatory Affairs Specialist
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6F, 7F and B1
Anyang-si, Gyeonggi-do 14055
REPUBLIC OF KOREA

November 7, 2024

Re: K242379
Trade/Device Name: LL Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 9, 2024
Received: August 12, 2024

Dear Woojin 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.

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
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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)*
K242379

Device Name
LL Implant System

Indications for Use *(Describe)*
The LL Implant System is intended to be use in the treatment of missing mandibular central and lateral incisors to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only. It is intended for delayed loading.

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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"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

Submitter Information

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Device Information

- Trade Name: LL Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: October 16 ,2024

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K191201, EM SA Implant System by Hiossen, Inc.

Reference Device

- K170394, Kisses Mini by ACHIMHAI Medical Corporation
- K112540, S-MiNi Implant System by Neobiotech Co., Ltd.
- K223924, LW Implant System by Ossvis Co., Ltd.
- K231079, LW Retraction Cap by Ossvis Co., Ltd.
- K182091, Osstem Abutment System by OSSTEM IMPLANT Co., Ltd.

Indication for Use:

The LL Implant System is intended to be use in the treatment of missing mandibular central and lateral incisors to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only. It is intended for delayed loading.

Device Description:
The LL Implant System consists of a one-piece implant and temporary cap.
The LL Mini Onebody Implant is made of CP Ti Grade 4(ASTM F67) with the surface treated by the SLA method. It has several design characteristics: submerged type, tapered body, sided cutting edge.
The LL Temporary Cap is made Polyoxymethylene (ASTM F1855) without any surface treatment.

The dimensions of subject devices are as following:

No	Device Name	Dimension
1	LL Mini Onebody Implant	Ø 2.7, 3.1 (D) x 8.5, 10.0, 11.5, 13.0 mm (L)
2	LL Temporary Cap	Ø 4.0 (D) x 9.6 mm (L)

The below table outlines the information of intended uses and surface treatment:

Device Name	Uses	Surface Treatment
LL Mini Onebody Implant	Implant is intended to replace the patient's natural tooth and restore chewing function.	SLA
LL Temporary Cap	Used to protect the upper part of LL Mini Onebody Implant in the oral cavity	None

The LL Mini Onebody Implant is provided sterile. And LL Temporary Cap is provided non-sterile, which are required to be sterilized by the end-user before use.

Materials:
- Dental Implant is fabricated from Pure titanium of ASTM F67
- Temporary Cap is fabricated from POM(Polyoxymethylene) of ASTM F1855

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Summaries of Technological Characteristics & Substantial Equivalence Discussion

LL Implant System

LL Mini Onebody Implant

	Subject Device	Predicate Device	Reference Device	Reference Device
510(k) #	K242379	K191201	K170394	K112540
Device Name	LL Implant System	EM SA Implant System	Kisses Mini	S-MiNi Implant System
Implant Name/Type	LL Mini Onebody Implant	Narrow Ridge Type	Post Type	Cement Type
Manufacturer	Ossvis Co., Ltd.	Hiossen, Inc.	Achimhai Medical Corporation	Neobiotech Co., Ltd.
Product Code	DZE	DZE	DZE	DZE
Regulation	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Appearance				
Indications for Use Statement	The LL Implant System is intended to be use in the treatment of missing **mandibular central and lateral incisors** to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only. It is intended for delayed loading.	The EM SA Implant System (DENTURE) is intended to be place in the bone of the upper or lower jaw arches providing support to dental prosthetic devices, specifically for denture stabilization to restore a patient's chewing function. It is intended for single use only. The EM SA Implant (NARROW RIDGE) is intended to be use in the treatment of missing **mandibular central and lateral incisors** to support dental prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended	The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading. The intended use of the 3.2 mm Internal Hex Fixture is limited to the replacement of maxillary lateral incisors and mandibular incisors. The intended use of the single-piece post type fixture is limited to the	The S-MiNi Implant System is divided into two types: - Cement Type The Cement type is indicated for use in the treatment of missing **maxillary lateral incisors or the mandibular central and lateral incisors** to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients. - Ball Type

		for single use only. It is intended for delayed loading.	replacement of **mandibular central and lateral incisors**. The ball-type single-piece implant is intended for stabilization and retention of overdentures.	The Ball type is designed for use in dental implant surgery. Ball type is intended for use in partially or fully edentulous mandibles and maxiliae, in support of overdentures. Ball type implants are for temporary use, only.
Structure	• Integrated Implant System (One body) • Tapered & Straight body shape • Threaded body design • Cutting edge with self- tapping	• Integrated Implant System (One body) • Tapered & Straight body shape • Threaded body design • Cutting edge with self- tapping	• Integrated Implant System (One body) • Tapered & Straight body shape • Threaded body design • Cutting edge with self- tapping	• Integrated Implant System (One body) • Tapered & Straight body shape • Threaded body design • Cutting edge with self -tapping
Diameter (Ø)	2.7, 3.1	2.5, 3.0	2.8, 3.0	2.0, 2.5, 3.0, 3.5
Length (mm)	8.5, 10.0, 11.5, 13.0	8.5, 10.0, 11.5, 13.0, 15.0	8.0, 9.5, 11.0, 12.5, 14.5	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
Material	Pure Titanium Grade 4 (ASTM F67)	Ti 6Al 4V ELI (ASTM F136)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Surface treatment	SLA	SLA	SLA	RBM
Substantial Equivalence Discussion				
The LL Mini Onebody Implant has the same intended use, design features, surface treatment, and sterilization as the primary predicate K191201. Both devices feature a one-body design and are intended for use at the same anatomical site, mandibular central and lateral incisors. The main differences between the subject and primary predicate devices are the material and dimensions. The primary predicate device is made of Ti-6Al-4V ELI and does not include diameters above 3.1 mm, whereas the subject device is made of Pure Titanium Grade 4. However, these differences in material and dimensions are covered by the reference devices. Reference device K170394 is made of Pure Titanium Grade 4 and undergoes SLA surface treatment and gamma sterilization. Reference device K112540 offers a wider range of dimensional combinations than the subject device, supporting substantial equivalence. Therefore, the subject device is considered substantially equivalent.				

LL Temporary Cap

	Subject Device	Reference Device	Reference Device
510(k) #	K242379	K231079	K182091
Device Name	LL Implant System	LW Retraction Cap	Osstem Abutment System
Abutment Name	LL Temporary Cap	LW Retraction Cap	Temporary Cap (Narrow Ridge)
Manufacturer	Ossvis Co., Ltd.	Ossvis Co., Ltd.	OSSTEM IMPLANT Co., Ltd.
Product Code	NHA	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Appearance			
Intended Use	Used in the oral cavity to protect the upper part of compatible one-piece implant from foreign substances such as plaque.	Used in the oral cavity to protect compatible abutments from foreign substances such as plaque.	Used in the oral cavity to protect compatible abutments from foreign substances such as plaque.
Diameter (Ø)	4.0	5.0, 6.0, 6.1, 6.7, 7.2, 7.7, 8.2, 8.7	4.0
Length (mm)	9.6	5.5, 7.0, 8.5	9.6
Material	POM (Polyoxymethylene) (ASTM F1855)	POM (Polyoxymethylene) (ASTM F1855)	Poly Carbonate
Sterilization	N/A	N/A	N/A
Surface treatment	N/A	N/A	N/A
Substantial Equivalence Discussion			
The LL Temporary Cap has the same indication for use, material, design feature, structure, surface treatment, and sterilization as the reference devices. The difference between the subject and reference device(K231079) is dimensions. However, it is used temporarily in the oral cavity and the size is designed to fit its compatible implant considering the intended use of the device. Also the dimensional difference is covered by the reference device(K182091). Therefore, we believe that the difference does not raise any serious issues in performance or safety, and the subject device is substantial equivalence to the predicate device.			

Non-Clinical Test Data

Below tests were performed on the subject device:

- Fatigue Testing according to ISO 14801:2016

The Below tests were performed for our previous submission devices and leveraged for the subject device:

- Gamma Sterilization Validation Test on LW Fixture according to ISO 11137-1, ISO 11137-2, and ISO 11137-3 referenced in K223924 (LW Implant System)
- End User Sterilization Validation Test Report on LW Retraction Cap according to ISO 17665-1, and ISO 17665-2 referenced in K231079 (LW Retraction Cap)
- Shelf-Life Test on LW Fixture according to ASTM F1980 referenced in K223924 (LW Implant System)
- Biocompatibility testing on LW Fixture according to ISO 10993-1:2018 referenced in K223924 (LW Implant System)
- Biocompatibility testing on LW Retraction Cap according to ISO 10993-1:2018 referenced in K231079 (LW Retraction Cap)
- LAL endotoxin testing on LW Fixture according to USP 43, <161> referenced in K223924 (LW Implant System)
- Surface Modification Information on LW Fixture referenced in K223924 (LW Implant System)

A brief description of the leveraged information is as follows.

[Surface Modification Information]
The surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The surface modification information with SLA (sand-blasted, large-grit, acid-etched) was provided. To compare surface modification between the subject and predicate device, surface roughness, surface composition analysis, SEM imaging, and ICP analysis were provided, and it demonstrates substantial equivalence.

[Gamma Sterilization Validation]
For devices delivered in a sterile state, such as Implants, a sterility assurance level (SAL) of 10^{-6} has been validated in accordance with ISO 11137-1 "*Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*". The validation took into account the worst-case scenario, and the results prove equivalence to the predicate device.

[End User Sterilization Validation]
The non-sterile abutments are intended to be sterilized by the end user. The recommended sterilization conditions have been validated through the end-user sterilization validation, following ISO 17665-1 "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 17665-2 "Sterilization of health care products – Moist heat – part 2: Guidance on the application of ISO 17665-1", and the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015". The validation considered the worst-case scenario, and the results demonstrated equivalence to the predicate device.

[Biocompatibility Testing]
Biocompatibility Testing was performed in accordance with ISO 10993-1 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and 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*". Cytotoxicity testing was performed according to ISO 10993-5.

[Shelf-life Testing]
The devices provided in a sterile state underwent Shelf-life testing in accordance with ASTM F1980, *"Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices"*. The worst-case scenario was tested, and the results demonstrated that the devices are equivalent to the predicate devices. The shelf-life for the Implant is 5 years, and throughout this time frame, the devices will function as intended without any degradation. Please note that the devices will not be labeled as *'non-pyrogenic'* when they are marketed.

[Fatigue Testing]
To evaluate performance of the subject device, Dynamic Fatigue, and Static Compression Strength tests were conducted according to the FDA guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" and ISO 14801:2016, "*Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*" under the worst-case scenario. As a result, our dental implant system is expected to function properly for its intended use, which is to replace the patient's natural tooth and restore chewing function.

[Bacterial Endotoxin Testing]
To address the presence of bacterial endotoxins, the devices corresponding to implants should meet the pyrogen limit specifications as specified in the FDA guidance document "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*" and USP <161> *"Medical Devices – Bacterial Endotoxin and Pyrogen Tests"*.
Therefore, our dental implants were tested for bacterial endotoxin under USP <85> *"Bacterial Endotoxins Test"*, and USP <161> *"Medical Devices – Bacterial Endotoxin and Pyrogen Tests"*.
The test results have met the acceptance criteria and demonstrated the substantial equivalence with the predicate device.

[MR Safety]
Non-clinical worst-case MRI review was performed to evaluate the subject devices 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 4 9.2 (2 01 9): 7 8 3-795), based on the entire system including all implants and abutments 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.

The non-clinical testing results demonstrate that the subject devices are substantially equivalent to the predicate devices.

Conclusion
The documentation submitted in this premarket notification demonstrates the LL Implant System is substantially equivalent to the primary predicate and reference devices.