August 8, 2023

Ossvis Co., Ltd.
℅ April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K223924
Trade/Device Name: LW Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 5, 2023
Received: July 5, 2023

Dear April 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,

Andrew I. Steen -S

Andrew I. 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)*
K223924

Device Name
LW Implant System

Indications for Use *(Describe)*
The LW Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, 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 LW Implant System is dedicated for two stage surgical procedures and is intended for delayed loading. Also, implants with diameters larger than 5mm are indicated for molar regions.

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

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Device Information

- Trade Name: LW 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: 08/08/2023

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

Primary Predicate

- K181138, IS-III active System by Neobiotech Co., Ltd.

Reference Device

- K153639, OneQ-SL s-Clean Implant System by Dentis Co., Ltd.
- K140091, Xpeed AnyRidge Internal Implant System by MegaGen Implant Co., Ltd.
- K140934, HIOSSEN Implant System by HiOSSEN Inc.
- K153350, IBS Implant System by Innobiosurg Co., Ltd.
- K161689, OSSTEM Implant System – Abutment by OSSTEM Implant Co., Ltd.
- K182091, Osstem Abutment System by OSSTEM Implant Co., Ltd.
- K211090, ZENEX Implant System by Izenimplant Co., Ltd.
- K172100, URIS OMNI System by TruAbutment Inc.

Indication for Use:
The LW Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, 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 LW Implant System is dedicated for two stage surgical procedures and is intended for delayed loading. Also, implants with diameters larger than 5mm are indicated for molar regions.

Device Description:

The LW Implant System consists of a fixture, cover screw, healing abutment, abutments, and abutment screw.

The Fixture is made of CP Ti Grade 4(ASTM F67) with the surface treated by the SLA method. It has several design characteristics: internal hex connection, submerged type, tapered body, sided cutting edge. The Cover Screw and Healing Abutment are made of CP Ti Grade 4(ASTM F67) without any surface treatment.
The Abutments consist of the LW Solid, LW Angled, LW Vis and LW Temporary Abutment, and LW Abutment Screw. The abutments have s-Line type and cuff type. The abutments are made of Ti-6Al-4V-ELI (ASTM F136).

<table>
<tr><th>Name</th><th>Uses</th><th>Surface Treatment</th><th>Fixture Connection</th></tr>
<tr><td>LW Cover Screw</td><td>The Cover Screw is used for protecting the inner hole of a fixture during the healing period.</td><td>N/A</td><td rowspan="2">Non-Hex</td></tr>
<tr><td>LW Healing Abutment</td><td>The Healing Abutment is used for protecting inner hole of a fixture and adjusting the appropriate gingival shape during the healing period</td><td>N/A</td></tr>
<tr><td>LW Solid Abutment</td><td rowspan="3">The Abutment is used as a support of prosthesis to restore the patient's chewing function.</td><td rowspan="3">N/A</td><td>Non-Hex</td></tr>
<tr><td>LW Angled Abutment</td><td>Hex 2.48 / Non-Hex</td></tr>
<tr><td>LW Vis Abutment</td><td>Hex 2.48 / Non-Hex</td></tr>
<tr><td>LW Temporary Abutment</td><td>The Temporary Abutment is used temporarily until making the final prosthesis to immediately restore a patient's chewing function after implantation as well as maintain an esthetic appearance. Maximum duration of Temporary Abutment is less than 6 months.</td><td>N/A</td><td>Hex 2.48 / Non-Hex</td></tr>
<tr><td>LW Abutment Screw</td><td>The Abutment Screw is used for connect fixture and abutment</td><td>N/A</td><td>Non-Hex</td></tr>
</table>

The LW Fixture, LW Cover Screw and LW Healing Abutment are provided sterile. The LW Solid Abutment, LW Angled Abutment, LW Vis Abutment, LW Temporary Abutment and LW Abutment Screw are provided non-sterile, which are required to be sterilized by the end-user before use.

The dimensions of subject devices are as following:

No	Device Name	Dimension
1	LW Fixture	Ø 4.2 x 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm (L) Ø 4.55 x 10.0, 11.5, 13.0, 15.0 mm (L) Ø 4.60 x 7.0, 8.5 mm (L) Ø 5.00 x 10.0, 11.5, 13.0, 15.0 mm (L) Ø 5.05 x 8.5 mm (L) Ø 5.07 x 7.0 mm (L) Ø 5.40 x 10.0, 11.5, 13.0, 15.0 mm (L) Ø 5.45 x 7.0, 8.5 mm (L) Ø 5.90 x 9.5, 11.0, 12.5 mm (L) Ø 5.95 x 7.0, 8.0 mm (L) Ø 6.55 x 9.5, 11.0, 12.5 mm (L)

		Ø 6.60 x 7.0, 8.0 mm (L) Ø 6.80 x 9.5, 11.0, 12.5 mm (L) Ø 6.85 x 7.0, 8.0 mm (L) Ø 7.25 x 11.0, 12.5 mm (L) Ø 7.30 x 9.5 mm (L) Ø 7.35 x 7.0, 8.0 mm (L) Ø 7.75 x 11.0, 12.5 mm (L) Ø 7.80 x 9.5 mm (L) Ø 7.85 x 7.0, 8.0 mm (L)
2	LW Cover Screw	Ø 3.6 (D) x 5.9 mm (H) Ø 3.75 (D) x 6.9 mm (H) Ø 3.9 (D) x 7.5 mm (H)
3	LW Healing Abutment	Ø 4.3, 4.8, 4.9, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3 (D) x 2.9 / 3.9 / 4.9 / 5.9 / 6.9 / 7.9 / 8.9 3.0 / 4.0 / 5.0 / 6.0 / 7.0 / 8.0 / 9.0 mm (H)
4	LW Solid Abutment	Ø 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (D) x 1.0, 2.0, 3.0, 4.0, 5.0 (G/H) x 4.0, 5.5, 7.0 mm (Post/H)
5	LW Angled Abutment	15, 17, 25, 30° (Angle) Ø 4.5, 5.0, 6.0 (D) x 2.0, 4.0 mm (G/H)
6	LW Vis Abutment	Ø 4.5, 4.6, 5.0, 6.0, 7.0 (D) x 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm (G/H) x 4.0, 5.5, 7.0 (Post/H)
7	LW Temporary Abutment	Ø 4.5 (D) x 1.0, 3.0 mm (G/H) x 10 mm (Post/H)
8	LW Abutment Screw	Ø 2.3 (D) x 8.34 mm (L)

Materials:

- The LW fixtures, Healing Abutment, and Cover Screw are fabricated from Pure titanium of ASTM F67
- LW abutments are fabricated from Ti-6Al-4V of ASTM F136

Summaries of Technological Characteristics & Substantial Equivalence Discussion

LW Fixture

	Subject Device	Primary Predicate	Reference Device	Reference Device
510(k) #	N/A	K181138	K153639	K140091
Device Name	LW Implant System	IS-III active System	OneQ-SL s Clean Implant System	Xpeed AnyRidge Internal Implant System
Manufacturer	Ossvis Co., Ltd.	Neobiotech Co., Ltd.	Dentis Co., Ltd.	MegaGen Implant 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 LW Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, 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 LW Implant System is dedicated for two stage surgical procedures and is intended for delayed loading. Also, implants with diameters larger than 5mm are indicated for molar regions.	The IS-III active System is indicated for use in partially or fully edentulous mandibles and maxillae, 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. IS-III active System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.	The OneQ-SL s Clean Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, 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. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.	The product is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially of fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Structure	• Internal Hex Connection • Submerged Fixture • Tapered & Straight body shape • sided cutting edge with self tapping	• Internal Hex Connection • Submerged Fixture • Tapered & Straight body shape • sided cutting edge with self-tapping	• Internal Hex Connection • Submerged Fixture • Tapered & Straight body shape • sided cutting edge with self-tapping	• Internal Hex Connection • Submerged Fixture • Tapered & Straight body shape
Diameter (Ø)	4.2, 4.55, 4.6, 5.0, 5.05, 5.07, 5.4, 5.45, 5.9, 5.95, 6.55, 6.6, 6.8, 6.85, 7.25, 7.3 7.35, 7.75, 7.8, 7.85	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular: 3.7, 3.9, 4.2, 4.7, 5.2 Wide: 6.0, 7.0, 8.0	4.0, 4.4, 4.9, 5.4, 5.9 (For normal ridge) 6.4, 6.9, 7.4, 7.9, 8.4 (For low ridge)
Length (mm)	7.0, 8.0, 8.5, 9.5, 10.0, 11.0, 11.5, 12.5, 13.0, 15.0	8.5, 10.0, 11.5, 13.0, 15.0 (For a diameter of 3.5)	Regular: 7.0, 8.0, 10.0, 12.0, 14.0 Wide: 7.0, 8.0, 10.0, 12.0	7.7, 9.2, 10.7, 12.2, 14.2, 17.2 (For normal ridge)

	(For diameters of 4.2 – 5.45) 7.0, 8.0, 8.5, 9.5, 10.0, 11.0, 11.5, 12.5 (For diameters of 5.9 – 7.85)	7.3, 8.5, 10.0, 11.5, 13.0, 15.0 (For a diameter of 4.0 – 5.5) 7.3, 8.5, 10.0, 11.5, 13.0 (For a diameter of 6.0 – 7.0)		7.9, 9.4, 10.9, 12.4, 14.4 (For low ridge)
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	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	SLA
Substantial Equivalence Discussion				
The LW Fixture has the same indication for use, material, design feature, structure, surface treatment, and sterilization as the primary predicate. The difference between the subject and primary predicate, K181138 is dimensions. The predicate device does not include all dimensional combinations of the subject device such as the fixture with diameter 4.2 x length 7.0 mm and fixtures with 12.5mm lengths and diameters above 7.0mm. However, the difference is covered by the reference devices such as K153639 and K140091 which have a wider range of diameter and length, and it does not raise an issue in performance or safety. Therefore, it is substantially equivalent.				

LW Cover Screw

	Subject Device	Reference Predicate	Reference Device
510(k) #	N/A	K153639	K140934
Device Name	LW Implant System	OneQ-SL s-Clean Implant System	HIOSSEN Implant System
Manufacturer	Ossvis Co., Ltd.	Dentis Co., Ltd.	HiOSSEN Inc.
Product Code	NHA	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Appearance			
Diameter (Ø)	3.6, 3.75, 3.9	3.6	3.03, 3.58, 3.25, 3.4, 3.75, 3.9
Height (mm)	5.9, 6.9, 7.5	5.9	5.25, 5.9, 6.25, 6.85, 6.9, 7.5
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Surface treatment	N/A	N/A	Anodizing
Substantial Equivalence Discussion			
The LW Cover Screw has the same indications for use, material, surface treatment, sterilization, and similar design as the primary predicate. The difference between subject and primary predicate is dimension. The subject device has a wider range of diameters and lengths. The reference device, K140934 was added since it encompasses the dimension range of the subject device and supports substantial equivalence.			

LW Healing Abutment

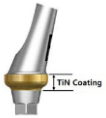
	Subject Device	**Reference Device**	**Reference Device**
510(k) #	N/A	K140934	K211090
Device Name	LW Implant System	HIOSSEN Implant System	ZENEX Implant System
Manufacturer	Ossvis Co., Ltd.	HiOSSEN Inc.	Izenimplant Co., Ltd.
Product Code	NHA	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Appearance			
Diameter (Ø)	4.3, 4.8, 4.9, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3	4.3, 4.8, 5.3, 6.3, 7.3	4.3 ~ 9.0
Height (mm)	2.9 – 9.0	3.0, 4.0, 5.0, 7.0	2.0 ~ 9.0
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Ti 6Al 4V ELI (ASTM F136)
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Surface treatment	N/A	N/A	N/A
Substantial Equivalence Discussion			
The LW Healing Abutment has the same intended use, material, surface treatment, sterilization and similar design as the reference device(K140934). The difference between subject and reference device, K140934 is the dimensions. The subject device has a wider range of diameters and heights. The wider range of dimensions is intended to meet the needs of each patient and does not raise an issue in safety and performance of the device. The reference device (K211090) encompasses the diameter range of the subject device and supports substantial equivalence.			

LW Solid Abutment

	Subject Device	**Reference Device**	**Reference Device**
510(k) #	N/A	K161689	K172100
Device Name	LW Implant System	OSSTEM Implant System - Abutment	URIS OMNI System
Abutment Name	LW Solid Abutment	Rigid Abutment	D Basis Abutment – Direct Type
Manufacturer	Ossvis Co., Ltd.	OSSTEM Implant Co., Ltd.	TruAbutment Korea Co., Ltd.
Product Code	NHA	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Appearance			
Diameter (Ø)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0	4.0, 4.6, 5.0, 6.0, 7.0	4.0, 4.5, 5.5, 6.5
G/H (mm)	1.0, 2.0, 3.0, 4.0, 5.0	1.0, 2.0, 3.0, 4.0, 5.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
P/H (mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0	4.0, 5.5, 7.0 mm

Material	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface treatment	Non-coating	TiN-coating	Non-coating
Substantial Equivalence Discussion			
The intended use, material, sterilization, dimension, and general design of the LW Solid Abutment are same as the reference devices, K161689. The difference between the two devices is surface treatment. To support this discrepancy, K172100 was added. Therefore, it is substantially equivalent.			

LW Angled Abutment

	Subject Device	**Reference Device**	**Reference Device**
510(k) #	N/A	K182091	K153350
Device Name	LW Implant System	Osstem Abutment System	IBS Implant System
Abutment Name	LW Angled Abutment	Angled Abutment	Angled Abutment
Manufacturer	Ossvis Co., Ltd.	OSSTEM Implant Co., Ltd.	Innobiosurg Co., Ltd.
Product Code	NHA	NHA	NHA
Regulation	21 CFR 872.3630	872.3630	21 CFR 872.3630
Appearance			
Connection Type	Hex, Non-Hex	Hex, Non-Hex	Internal Hex
Diameter (Ø)	4.5, 5.0, 6.0	4.0, 4.5, 5.0, 6.0	4.0, 4.5, 5.0
G/H (mm)	2.0, 4.0	2.0, 4.0	1.0, 2.0, 3.0, 4.0
P/H (mm)	8.0	8.0	1.0, 2.0, 3.0, 4.0
Angle (°)	15, 17, 25, 30°	17°	15, 25, 30°
Material	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface treatment	Non-coating	TiN-coating	Non-coating
Substantial Equivalence Discussion			
The LW Angled Abutment has the same intended use, material, sterilization, and similar design as the reference devices, K182091. The difference between the two devices is angulation and surface treatment. To support angulation and surface treatment, K153350 was added. Therefore, it is substantially equivalent.			

LW Vis Abutment

	Subject Device	Reference Device	Reference Device
510(k) Number	N/A	K182091	K172100
Device Name	LW Implant System	Osstem Abutment System	URIS OMNI System
Abutment Name	LW Vis Abutment	Transfer Abutment	D Basis Abutment – Cemented Type
Manufacturer	Ossvis Co., Ltd.	OSSTEM Implant Co., Ltd.	TruAbutment Korea Co., Ltd.
Product Code	NHA	NHA	NHA
Regulation Number	872.3630	872.3630	21 CFR 872.3630
Appearance			
Connection Type	Hex, Non-Hex	Hex, Non-Hex	Hex, Non-Hex
Diameter (Ø)	4.5, 4.6, 5.0, 6.0, 7.0	4.0, 4.6, 5.0, 6.0, 7.0	4.0, 4.5, 5.5, 6.5
G/H (mm)	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
P/H (mm)	4.0, 5.5, 7.0	4.0, 5.5, 7.0	4.0, 5.5, 7.0 mm
Material	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface treatment	Non-coating	TiN-coating	Non-coating
Substantial Equivalence Discussion			
The intended use, material, sterilization, dimension, and general design of the LW Solid Abutment are same as the reference devices, K182091. The difference between the two devices is surface treatment. To support this discrepancy, K172100 was added. Therefore, it is substantially equivalent.			

LW Temporary Abutment

	Subject Device	Reference Device
510(k) #	N/A	K161689
Device Name	LW Implant System	OSSTEM Implant System - Abutment
Abutment Name	LW Temporary Abutment	Temporary Abutment
Manufacturer	Ossvis Co., Ltd.	OSSTEM Implant Co., Ltd.
Product Code	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630
Appearance		
Connection Type	Hex, Non-Hex	Hex, Non-Hex
Diameter (Ø)	4.5	4.0, 4.5
G/H (mm)	1.0, 3.0	1.0, 3.0
Post/H (mm)	10	10

Material	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Maximum duration	Less than 6 months	Less than 6 months
Surface treatment	N/A	N/A
Substantial Equivalence Discussion		
The LW Temporary Abutment has the same intended use, surface treatment, sterilization, fixture connection type and similar design as the reference device, K161689. Although the post shape differs from the reference device, we do not consider the differences between devices a serious thing that affect the safety and effectiveness of the device since the device is temporarily used in the human body unlike other permanent abutments. Therefore, it is substantially equivalent.		

LW Abutment Screw

	Subject Device	**Reference Device**
510(k) #	N/A	K161689
Device Name	LW Implant System	OSSTEM Implant System - Abutment
Abutment Name	LW Abutment Screw	Abutment Screw
Manufacturer	Ossvis Co., Ltd.	OSSTEM Implant Co., Ltd.
Product Code	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630
Appearance		
Diameter (Ø)	2.3 mm	2.0, 2.05, 2.2, 2.3, 2.5 mm
Length (mm)	8.34mm	3.35, 5.6, 7.5, 8.35, 9.6, 10.2 mm
Material	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface treatment	N/A	N/A
Substantial Equivalence Discussion		
The LW Abutment Screw has the identical to the reference device, K161689 in intended use, design, material, and surface treatment. Device comparison shows the equivalence between the subject and predicate device.		

Non-Clinical Test Data

The following non-clinical tests were conducted on the subject devices to prove the safety and performance:

- Gamma Sterilization Validation Test under ISO 11137-1, ISO 11137-2, and ISO 11137-3
- End User sterilization Validation under ISO 17665-1 and ISO 17665-2
- Shelf-life Test under ASTM F1980
- Biocompatibility Tests - cytotoxicity according to ISO 10993-5
- Fatigue test under ISO 14801
- Bacterial Endotoxin Testing (LAL) under USP <85>, and USP <161>

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 (K181138), surface roughness, surface composition analysis, SEM imaging, and ICP analysis were provided, and it demonstrates substantial equivalence.

For devices delivered sterile such as Fixture, Healing Abutment, and Cover Screw, a sterility assurance level (SAL) of 10^{-6} have been validated in accordance with 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". The validation took into account the worst-case scenario, and the results prove equivalence to the predicate device.

For devices delivered non-sterile to be end-user sterilized, the recommended sterilization condition has been validated through the end-user sterilization validation, according to 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 to applicable recommendations in the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015". The worst-case scenario had been considered in the validation, and the results showed equivalence to the predicate device.

Shelf-life Testing was performed on the devices provided sterile 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 Fixture, Healing Abutment, and Cover Screw is 5 years, and the devices will function adequately as intended without any degradation during the shelf-life. Please note that the devices will not be labeled as *'non-pyrogenic'* when they are marketed.

Biocompatibility Testing was performed according to ISO 10993-1 "*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"*. Cytotoxicity testing was performed according to ISO 10993-5. The result demonstrated the biocompatibility of the material used.

To evaluate the performance of subject devices, 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.

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 implant fixtures were tested for bacterial endotoxin under USP <85> *"Bacterial Endotoxins Test"*, and USP <161> *"Medical Devices – Bacterial Endotoxin and Pyrogen Tests".*The test result have met the acceptance criteria and demonstrated the substantial equivalence with the predicate device.

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 fixtures 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 device is substantially equivalent to the predicate device.

Conclusion

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