March 25, 2024

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

Re: K233167
Trade/Device Name: LW Implant System - Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 27, 2024
Received: February 28, 2024

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 (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.

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
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)*
K233167

Device Name
LW Implant System - Abutment

Indications for Use *(Describe)*
The LW Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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**
Ossvis Co., Ltd.
Woo Jin Lee
7F and B1, 38, Burim-ro 170beon-gil, Dongan-gu,
Anyang-si, Gyeonggi-do, Republic of Korea
Email: wjl316@ossvis.com
Tel. +82-31-360-0082
Fax. +82-31-360-0058

**Official Correspondent**
Withus Group Inc.
April Lee
106 Superior,
Irvine, CA 92620 USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

**Device Information**

- Trade Name: LW Implant System – Abutment
- Common Name: Endosseous dental implant abutment
- Classification Name: Endosseous Dental Implant Abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date Prepared: 03/20/2024

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

**Primary Predicate**

- K161689, OSSTEM Implant System – Abutment by OSSTEM Implant Co., Ltd.

**Reference Device**

- K182091, Osstem Abutment System by OSSTEM Implant Co., Ltd.
- K223924, LW Implant System by OSSVIS Co., Ltd.

**Indications for Use:**
The LW Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

**Device Description:**

The LW Implant System - Abutment consists of the LW Solid, LW Angled, and LW Vis Abutment. The abutments have s-Line type and cuff type. The abutments are made of Ti-6Al-4V-ELI (ASTM F136), and they are provided non-sterile, which are required to be sterilized by the end-user before use.

The LW Implant System – Abutment is compatible with the LW Fixture and LW Abutment Screw in the LW Implant System, K223924.

| Name | Uses | Surface Treatment | Fixture Connection |
|---|---|---|---|
| LW Solid Abutment | The Abutment is used as a support of prosthesis to restore the patient's chewing function. | TiN-Coating (Partial, Full) | Hex 2.48 / Non-Hex |
| LW Angled Abutment | | None | Hex 2.48 (Type A, B) / Non-Hex |
| | | TiN-Coating (Partial, Full) | |
| LW Vis Abutment | | TiN-Coating (Partial, Full) | Hex 2.48 / Non-Hex |

The dimensions of subject devices are as following:

| No | Device Name | Dimension |
|---|---|---|
| 1 | LW Solid Abutment | Ø 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (D)<br>x 1.0, 2.0, 3.0, 4.0, 5.0 (G/H)<br>x 4.0, 5.5, 7.0 mm (Post/H) |
| 2 | LW Angled Abutment | 15, 17, 25, 30° (Angle)<br>Ø 4.5, 5.0, 6.0 (D)<br>x 2.0, 4.0 mm (G/H)<br>X 8.0 mm (P/H) |
| 3 | LW Vis Abutment | Ø 4.5, 4.6, 5.0, 6.0, 7.0 (D)<br>x 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 mm (G/H)<br>x 4.0, 5.5, 7.0 (Post/H) |

**Materials:**

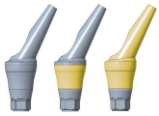
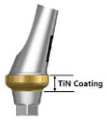
- The subject abutments are fabricated from Ti-6Al-4V of ASTM F136

## Summaries of Technological Characteristics & Substantial Equivalence Discussion

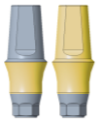
**LW Solid Abutment**

| | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| 510(k) # | N/A | K161689 | K223924 |
| Device Name | LW Implant System – Abutment | OSSTEM Implant System - Abutment | LW Implant System |
| Abutment Name | LW Solid Abutment | Rigid Abutment | LW Solid Abutment |
| Manufacturer | Ossvis Co., Ltd. | OSSTEM Implant Co., Ltd. | Ossvis 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, 5.0, 5.5, 6.0, 6.5, 7.0 |
| 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 |
| P/H (mm) | 4.0, 5.5, 7.0 | 4.0, 5.5, 7.0 | 4.0, 5.5, 7.0 |
| Material | Ti 6Al 4V ELI (ASTM F136) | Ti 6Al 4V ELI (ASTM F136) | Ti 6Al 4V ELI (ASTM F136) |
| Surface treatment | TiN-coating | TiN-coating | Non-coating |
| Sterilization | End User Sterilization | End User Sterilization | End User Sterilization |
| **Substantial Equivalence Discussion** | | | |
| The LW Solid Abutment is intended for the same use as the primary predicate, K161689. The material, surface treatment, sterilization method, and dimensions are identical to the primary predicate device. The LW Solid Abutment with non-coating was cleared under K223924. This submission seeks to introduce a different surface treatment such as TiN-coated surface treatment. The device comparison chart demonstrates the substantial equivalence between the subject and predicate devices. | | | |

**LW Angled Abutment**

| | Subject Device | Reference Device | Reference Device |
|---|---|---|---|
| 510(k) # | N/A | K182091 | K223924 |
| Device Name | LW Implant System - Abutment | Osstem Abutment System | LW Implant System |
| Abutment Name | LW Angled Abutment | Angled Abutment | LW Angled Abutment |
| Manufacturer | Ossvis Co., Ltd. | OSSTEM Implant Co., Ltd. | Ossvis 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 | Hex, Non-Hex |
| Diameter (Ø) | 4.5, 5.0, 6.0 | 4.0, 4.5, 5.0, 6.0 | 4.5, 5.0, 6.0 |
| G/H (mm) | 2.0, 4.0 | 2.0, 4.0 | 2.0, 4.0 |
| P/H (mm) | 8.0 | 8.0 | 8.0 |
| Angle (°) | 15, 17, 25, 30° | 17° | 15, 17, 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 | TiN-coating | Non-coating |
| Sterilization | End User Sterilization | End User Sterilization | End User Sterilization |
| **Substantial Equivalence Discussion** | | | |
| The indications, material, surface treatment, angles, sterilization method, and dimensions are identical to the reference device, K182091. The non-coated LW Angled Abutment with Hex B type was previously granted clearance under K223924. This submission seeks to include TiN-coated abutments and the Hex A type Angled Abutment. Therefore, the subject device exhibits substantial equivalence to the reference devices. | | | |

**LW Vis Abutment**

| | **Subject Device** | **Reference Device** | **Reference Device** |
|---|---|---|---|
| 510(k) # | N/A | K182091 | K223924 |
| Device Name | LW Implant System - Abutment | Osstem Abutment System | LW Implant System |
| Abutment Name | LW Vis Abutment | Transfer Abutment | LW Vis Abutment |
| Manufacturer | Ossvis Co., Ltd. | OSSTEM Implant Co., Ltd. | Ossvis Co., Ltd. |
| Product Code | NHA | NHA | NHA |
| Regulation | 872.3630 | 872.3630 | 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 | 4.5, 4.6, 5.0, 6.0, 7.0 |
| 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, 7.0 |
| P/H (mm) | 4.0, 5.5, 7.0 | 4.0, 5.5, 7.0 | 4.0, 5.5, 7.0 |
| Material | Ti 6Al 4V ELI (ASTM F136) | Ti 6Al 4V ELI(ASTM F136) | Ti 6Al 4V ELI (ASTM F136) |
| Surface treatment | TiN-coating | TiN-coating | Non-coating |
| Sterilization | End User Sterilization | End User Sterilization | End User Sterilization |
| **Substantial Equivalence Discussion** | | | |
| The indications, material, surface treatment, sterilization method, and dimensions are identical to the reference device, K182091. The LW Vis Abutment with non-coating was cleared under K223924. The aim of the submission is to add a different surface treatment such as TiN-coated surface treatment. The device comparison chart demonstrates the substantial equivalence between the subject and reference devices. | | | |

**Non-Clinical Test Data**

The following non-clinical tests were performed on the subject device or previously provided in a reference device, and the test results support that the subject device is substantially equivalent to the predicate devices.

- 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 TiN(Titanium Nitride) coating information such as chemical composition analysis, coating thickness, SEM imaging, surface roughness, scratch test data was provided. The surface treatment applied to the subject devices demonstrates substantial equivalence to the predicate.

- End User sterilization Validation under ISO 17665-1 and ISO 17665-2
  The end-user sterilization validation under ISO 17665-1 and ISO 17665-2 was included in a previously cleared submission identified as reference device (K223924).

- Biocompatibility Tests under ISO 10993-1
  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.

- Fatigue test under ISO 14801
  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.

- MRI Safety Information
  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 devices are substantially equivalent to the predicate devices.

**Conclusion**

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