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

December 5, 2024

Re: K242703
Trade/Device Name: LW Pre-milled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 6, 2024
Received: September 9, 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.

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
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)*
K242703

Device Name
LW Pre-milled Abutment

Indications for Use *(Describe)*
LW Pre-milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

No.	Compatible Implant	Implant Diameter (mm)	Platform Diameter (mm)
1	LW Implant	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	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
2	LW Narrow Implant	3.75/3.77	3.75/3.77

LW Pre-milled Abutment is intended for use with the LW Implant System in the chart. All digitally designed abutments for use with LW Pre-milled Abutment are intended to be manufactured at the OSSVIS-validated milling center.

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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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
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Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: LW Pre-milled Abutment
- Common Name: Endosseous dental implant abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date Prepared: 11/29/2024

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

Primary Predicate

- K210362, s-Clean Pre-Milled Abutment by Dentis Co., Ltd.

Reference Device

- K203344, Premilled Titanium Block System by InnoBioSurg Co., Ltd.
- K223924, LW Implant System by Ossvis Co., Ltd.
- K233167, LW Implant System – Abutment by Ossvis Co., Ltd.
- K233808, LW Narrow Implant System by Ossvis Co., Ltd.

Indication for Use:
LW Pre-milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

No.	Compatible Implant	Implant Diameter (mm)	Platform Diameter (mm)
1	LW Implant	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	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
2	LW Narrow Implant	3.75/3.77	3.75/3.77

LW Pre-milled Abutment is intended for use with the LW Implant System in the chart. All digitally designed abutments for use with LW Pre-milled Abutment are intended to be manufactured at the OSSVIS-validated milling center.

Device Description:
The LW Pre-milled Abutment is made of Ti-6Al-4V-ELI (ASTM F136), and it is provided non-sterile, which is required to be sterilized by the end-user before use. The subject abutment is indicated for cemented or "Screw-and Cement-Retained Prosthesis(SCRP)" restorations.

To produce patient-specific abutments, the cylindrical section of LW Pre-milled Abutment is customized by machining it using CAD/CAM technology. Each patient-specific abutment is custom-prescribed by the clinician.

Abutment Name	Uses	Surface Treatment	Fixture Connection
LW Pre-milled Abutment	The Abutment is used as a support of prosthesis to restore the patient's chewing function.	N/A	Hex 2.48 / Non-Hex
LW Narrow Pre-milled Abutment			Hex 2.08 / Non-Hex

LW Pre-milled Abutment is compatible with following Implant System.
1) LW Pre-milled Abutment

Proprietary Name	LW Implant System
Pre-market Submission Number	K223924
Compatible Implant Device Name	LW Implant
Implant Interface Connection Type/Size (mm)	Internal Connection Type/2.5
Type of Implant-Abutment Connection	Hex/Non-Hex

LW Pre-milled Abutment is used with an LW Abutment Screw in LW Implant System(K223924).

2) LW Narrow Pre-milled Abutment

Proprietary Name	LW Narrow Implant System
Pre-market Submission Number	K233808
Compatible Implant Device Name	LW Narrow Implant
Implant Interface Connection Type/Size (mm)	Internal Connection Type/2.1
Type of Implant-Abutment Connection	Hex/Non-Hex

LW Narrow Pre-milled Abutment is used with an LW Narrow Abutment Screw in LW Narrow Implant System(K233808).

The design envelope for Patient-Specific Abutment are as follows:

	LW Pre-milled Abutment (Internal Connection 2.5)	LW Narrow Pre-milled Abutment (Internal Connection 2.1)
Diameter	4.5-7.0 mm	4.0, 4.5 mm
Length	Straight: 7.9 - 16.9 mm Angled: 12.9, 14.9 mm	
Minimum gingival height	1.0 mm	
Maximum gingival height	7.0 mm	
Minimum wall thickness	0.4 mm	
Minimum post height for single-unit restorations (length above the abutment collar / gingival height)	4.0 mm	
Maximum angulation	30˚	

Materials:
- LW Pre-milled Abutment is fabricated from Ti-6Al-4V of ASTM F136

Summaries of Technological Characteristics & Substantial Equivalence Discussion

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate</th><th>Reference Device</th></tr>
<tr><td>510(k) #</td><td>K242703</td><td>K210362</td><td>K203344</td></tr>
<tr><td>Device Name</td><td>LW Pre-milled Abutment</td><td>s-Clean Pre-Milled Abutment</td><td>Premilled Titanium Block System</td></tr>
<tr><td>Manufacturer</td><td>Ossvis Co., Ltd.</td><td>Dentis Co., Ltd.</td><td>InnoBioSurg Co., Ltd.</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>NHA</td></tr>
<tr><td>Regulation</td><td>21 CFR 872.3630</td><td>21 CFR 872.3630</td><td>21 CFR 872.3630</td></tr>
<tr><td>Indications for Use Statement</td><td>LW Pre-milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Compatible Implant</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>LW Implant</td><td>Ø4.2/4.55/ 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</td><td>Ø4.2/4.55/ 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</td></tr>
<tr><td>LW Narrow Implant</td><td>Ø3.75/3.77</td><td>Ø3.75/3.77</td></tr>
</table>
LW Pre-milled Abutment is intended for use the LW Implant System in the chart. All digitally designed abutments for use with LW Pre-milled Abutment are intended to be manufactured at the OSSVIS-validated milling center.</td><td>s-Clean Pre-Milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>s-Clean SQ-SL Fixture</td><td>Ø5.8</td><td>Ø4.3</td></tr>
<tr><td></td><td>Ø6.8</td><td>Ø4.5</td></tr>
</table>
s-Clean Pre-Milled Abutment is intended for use with the s-Clean SQ-SL Fixtures in the chart. All digitally designed abutments for use with s-Clean Pre-Milled Abutment are intended to be manufactured at a Dentis validated milling center.</td><td>Premilled Titanium Block System is intended for use with dental implants as a support for single or multiple tooth
prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>IBS Implant System</td><td>3.8/4.3/4.8/ 5.3/5.8/6.3</td><td>3.8/4.3/4.8/ 5.3/5.8/6.3</td></tr>
<tr><td>IBS Implant System</td><td>3.5/4.0/4.5/ 5.0/5.5/6.0/6.5</td><td>3.5/4.0/4.5/ 5.0/5.5/6.0/6.5</td></tr>
<tr><td>Magicore System</td><td>4.0/4.5/5.0/ 5.5/6.0/6.5</td><td>4.0/4.5/5.0/ 5.5/6.0/6.5</td></tr>
<tr><td>IBS Implant System II</td><td>3.5/3.8/4.0/4.5/ 5.0/5.5/6.0/6.5</td><td>3.5/3.8/4.0/4.5/ 5.0/5.5/6.0/6.5</td></tr>
</table>
Premilled Titanium Block System is intended for use with the IBS implant system, Magicore System and IBS Implant System II in the chart. All digitally designed abutments for use with Premilled Titanium Block System are intended to be manufactured at a Innobiosurg validated milling center.</td></tr>
<tr><td>Gingival Height (mm)</td><td>Min 1.0 / Max 7.0
(Patient-specific milling design envelope)</td><td>Not identified
(Patient-specific milling design envelope)</td><td>Min 0.5 / Max 7.0
(Patient-specific milling design envelope)</td></tr>
<tr><td>Post Height (mm)</td><td>Min 4.0
(Patient-specific milling design envelope)</td><td>Not identified
(Patient-specific milling design envelope)</td><td>Min 4.0
(Patient-specific milling design envelope)</td></tr>
<tr><td>Connection Type</td><td>Hex, Non-Hex</td><td>Hex, Non-Hex</td><td>Hex, Non-Hex</td></tr>
</table>

Type of Retention	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Material	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface treatment	N/A	N/A	N/A
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalence Discussion			
The subject device is substantially equivalent to the predicate device (K210362) in terms of indications for use, material, surface treatment, sterilization, and design. Although there are differences in dimensions and compatible implant systems, these do not alter the intended use or affect the safety and performance of the device. The subject device is designed, manufactured and verified in compliance with the FDA's Class II special controls guidance document root-food endosseous dental implants and endosseous dental implant abutments. The implant-to-abutment compatibility and performance of the device have been demonstrated through fatigue testing. Additionally, we included the reference device (K203344) to support the 7.0 mm gingival height. The reference device has the same intended use, which is to support the prosthesis in order to restore the patient's chewing function. It is also substantially equivalent to the subject device in terms of design and manufacturing characteristics. Therefore, we believe that the subject device is substantially equivalent to the predicate device.			

Non-Clinical Test Data

Below tests were performed on the subject device:

- End User Sterilization Validation Test according to ISO 17665-1,-2

In this submission, we leverage our previous 510(k) submission data for the below test data:

- Fatigue Testing according to ISO 14801:2016 referenced in K233808 and K233167
- Biocompatibility Testing on Abutments according to ISO 10993-1: 2018 referenced in K223924

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 Tests

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*".

Fatigue Test

To evaluate the performance of subject devices, Dynamic Fatigue and Static Compression Strength tests were conducted according to the FDA guidance document *titled '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

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). 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 Pre-milled Abutment is substantially equivalent to the primary predicate device.