9-14-23

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

Re: K231079
Trade/Device Name: LW Retraction Cap
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 11, 2023
Received: August 11, 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 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 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231079

Device Name
LW Retraction Cap

Indications for Use *(Describe)*
The LW Retraction Cap 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.

510(k) Summary

Submitter
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Device Information

- Trade Name: LW Retraction Cap
- 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: 09/12/2023

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

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

Indication for Use:
The LW Retraction Cap is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Device Description:

The LW Retraction Cap is a component of the LW Implant System (K223924), and it is used with the LW Solid Abutment and LW Vis Abutment of the LW Implant System.

Name	Uses	Surface Treatment
LW Retraction Cap	Used to protect the LW Solid Abutment and LW Vis Abutment in the oral cavity	N/A

The LW Retraction Cap is made of POM(Polyoxymethylene(ASTM F1855)) and provided non-sterile, which is required to be sterilized by the end-user before use.

The dimensions of subject device are as following:

No	Device Name	Dimension
1	LW Retraction Cap	Ø 5.0, 6.0, 6.1, 6.7, 7.2, 7.7, 8.2, 8.7 mm (D) x 5.5, 7.0, 8.5 mm (L)

Materials:

- LW Retraction Cap is fabricated from POM(Polyoxymethylene) of ASTM F1855

Summaries of Technological Characteristics & Substantial Equivalence Discussion

LW Retraction Cap

	Subject Device	Predicate Device
510(k) #	K231079	K161689
Device Name	LW Retraction Cap	OSSTEM Implant System - Abutment
Abutment Name	LW Retraction Cap	Rigid Retraction Cap
Manufacturer	Ossvis Co., Ltd.	OSSTEM Implant Co., Ltd.
Product Code	NHA	NHA
Regulation	21 CFR 872.3630	21 CFR 872.3630
Appearance		
Indications for Use Statement	The LW Retraction Cap is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The OSSTEM Implant System – Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Uses	Used to protect the LW Solid Abutment and LW Vis Abutment in the oral cavity	Used for the protection of the Rigid Abutment on the oral cavity
Diameter (mm)	5.0, 6.0, 6.1, 6.7, 7.2, 7.7, 8.2, 8.7	4.8, 6.0, 6.6, 7.7, 8.7
Length (mm)	5.5, 7.0, 8.5	5.5, 7.0, 8.5
Material	POM (Polyoxymethylene) (ASTM F1855)	POM (Polyoxymethylene) (ASTM F1855)
Sterilization	N/A	N/A
Surface treatment	N/A	N/A
Maximum duration for clinical use	30 days	Unknown
Substantial Equivalence Discussion		
The LW Retraction Cap 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 is dimensions. However, the difference does not raise any serious issues in performance or safety because it is used temporarily in the oral cavity and the size fits its compatible abutment considering the intended use of the device. Therefore, the subject device is substantial equivalence to the predicate device.		

Non-Clinical Test Data

The following non-clinical tests were conducted to prove the safety and performance of the LW Retraction Cap.

- End User Sterilization Validation

The subject device is delivered non-sterile and is intended to be sterilized by the end user. The recommended sterilization conditions have been validated by performing 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"* and ISO 17665-2 *"Sterilization of health care products – Moist heat – part 2: Guidance on the application of ISO 17665-1"*. The worst-case scenario was considered in the test, and the results showed equivalency to the predicate device.

- Biocompatibility Tests

Cytotoxicity Testing was performed according to ISO 10993-5 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"*.

- Performance Tests

Tests for appearance and dimensions were performed to evaluate the performance of the LW Retraction Cap. The test results satisfied the acceptance criteria and support that the device will fit its compatible abutment and function properly as its intended use, which is to cover and protect an abutment.

The non-clinical testing results have met the acceptance criteria and demonstrated the substantial equivalence with the predicate device.

Conclusion

The documentation submitted in this premarket notification demonstrates the LW Retraction Cap is substantially equivalent to the primary predicate device.