February 26, 2020

SHINHUNG MST Co., Ltd.
Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K200189
Trade/Device Name: Luna Dental Implant System - Healing Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 13, 2020
Received: January 27, 2020

Dear Priscilla Chung:

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,

for Srinivas Nandkumar, Ph.D.
Director
Implantable Dental Devices Team
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Luna Dental Implant System – Healing Abutment

Indications for Use *(Describe)*
The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

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
(K200189)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 02/26/2020

1. Submitter

SHINHUNG MST Co., Ltd.
110-2, Donghwagongdan-Ro
Munmak-Eup
Wonju Si, Gangweondo, Republic of Korea
220-801
Tel. +82-33-730-1901

2. Official Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200, Irvine CA 92620
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Luna Dental Implant System – Healing Abutment
- Common Name: Implant Abutment
- Classification Name: Endosseous Dental Implant Abutment
- Product Code: NHA
- Classification regulation: 21CFR 872.3630

4. Predicate Device:

- Luna Dental Implant System (K123155) by SHINHUNG MST Co., Ltd.
- TS IMPLANT SYSTEM (K121585) by Osstem Co., Ltd.

5. Description:

The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. This submission is to get clearance on the modification of the healing abutments that are used with the fixture cleared under K123155 and K160106.

The healing abutment is to be connected to the implant and is to heal gingiva before

setting abutment on the implant in the oral cavity. It is made of commercially pure titanium alloy Gr4. It offers narrow and regular platform types, and the narrow type has anodizing surface treatment in purple to be distinguished from the regular type.

N (Narrow) Type

- 4.3mm(Dia) x 9.2/10.2/11.2/12.2/13.2mm (Length)
- 4.8mm(Dia) x 9.2/10.2/11.2/12.2/13.2mm (Length)

R (Regular) Type

- 4.3mm(Dia) x 10/11/12/13/14mm (Length)
- 4.8mm(Dia) x 10/11/12/13/14mm (Length)
- 5.8mm(Dia) x 10/11/12/13/14mm (Length)
- 6.3mm(Dia) x 10/11/12/13/14mm (Length)

6. Indication for use:

The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

7. Basis for Substantial Equivalence

The Luna Dental Implant System – Healing Abutment is substantially equivalent to its predicate device (K123155) in terms of indications for use, raw material, and design. The differences are in body design and size range. The design change does not raise a question in substantial equivalence since the change is not significant. We have identified a reference device that encompass the size range of the subject device. Based on the information submitted here in we conclude that the subject device is substantially equivalent to the predicate devices.

Device Name	Subject Device	Predicate Device	Reference Device
Manufacturer	SHINHUNG MST Co., Ltd	SHINHUNG MST Co., Ltd	Osstem Co., Ltd.
510(k) Number	K200189	K123155	K121585
Device Name	Luna Dental Implant System – Healing Abutment	Luna Dental Implant System	TS IMPLANT SYSTEM
Form	Abutment	Implant and Abutment	Implant and Abutment
Indications for use	The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	The TS Implant System is indicated for use in partially or roily edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture. TS Implant System is compatible with abutment in the ET/SS Implant System.
Sterilization	It is supplied sterile (Gamma radiation)	It is supplied sterile (Gamma radiation)	It is supplied sterile (Gamma radiation)

Shape	NP(Anodizing)  RP(Non-Anodizing) 	NP (Anodizing)  RP(Anodizing) 	(Non-Anodizing) 
Material	Ti-Gr4	Ti-Gr4	Ti-Gr4
Size	1) N type -Diameter: 4.3~4.8mm -Height: 4.0, 5.0, 6.0, 7.0, 8.0mm 2) R type -Diameter: 4.3~6.3mm -Height: 4.0, 5.0, 6.0, 7.0, 8.0mm	1) N type -Diameter: 4.5~6.0mm -Height: 2.0, 3.5, 5.0, 7.0mm 2) R type -Diameter: 4.5~7.0mm -Height: 2.0, 3.5, 5.0, 7.0mm	1) N type -Diameter: 4.0~4.5mm -Height: 3.0, 4.0, 5.0, 7.0, 9.0mm 2) R type -Diameter: 4.0~8.0mm -Height: 3.0, 4.0, 5.0, 7.0, 9.0mm

8. Non-Clinical Testing

Risk analysis was conducted according to ISO14971 to evaluate the effect of the modification. The risk assessment did not show that the device changes affected biocompatibility, sterilization, and shelf life such that the testing in the prior (predicate) file is still applicable.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the Luna Dental Implant System – Healing Abutment has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the similar design,
* incorporate the same material and the sterilization method.

Based on the similarities, we conclude that the Luna Dental Implant System – Healing Abutment is substantially equivalent to the predicate device.