February 3, 2023

Shinhung MST Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. , STE 160
Irvine, California 92612

Re: K223395
Trade/Device Name: Luna Dental Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 1, 2022
Received: November 8, 2022

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223395

Device Name
Luna Dental Implant System

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. The Luna Dental Implant System is intended for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.

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.

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510(k) Summary

(K223395)

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

Date: 2/2/2023

1. Submitter

SHINHUNG MST CO., LTD.
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Wonju-si, Gangwon-do, Republic of Korea, 26365

Tel: +82-33-730-1901

2. U.S Agent/Contact Person

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3. Device

- Trade Name: Luna Dental Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: NHA
- Classification regulation: 21CFR 872.3640

4. Predicate Device:

- Primary predicate device:
  LUNA DENTAL IMPLANT SYSTEM by SHINHUNG MST CO., LTD (K123155)

- Reference predicate device:
  LUNA DENTAL IMPLANT SYSTEM by SHINHUNG MST CO., LTD (K160106)
  ET/SS IMPLANT SYSTEM by OSSTEM IMPLANT CO.,LTD (K120847)
  Temporary Snap Abutment by Nobel Biocare AB (K161435)

5. Description:

The Luna Dental Implant System is a device of pure titanium (ASTM F67) and titanium alloy (ASTM Fl136) intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It consists of fixture, abutment, mount, mount screw, cover screw. This 510k is intended to add the new models of the following abutments to the Luna Dental Implant System.

- Healing Abutment
- Duo Abutment
- Duo Plus Abutment
- Temporary Abutment

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. The Luna Dental Implant System is intended for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.

7. Basis for Substantial Equivalence

Comparison Chart

▪ Healing Abutment

Device Name	Subject Device	Primary Predicate Device	Reference Device
Manufacturer	SHINHUNG MST CO., LTD.	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.
Device Name	Healing Abutment	Healing Abutment	Healing Abutment
Design			
510(k) Number	K223395	K123155	K120847
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	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 ET/SS 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

	chewing function. The Luna Dental Implant System is intended for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.		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.
Diameter (mm)	4.0 ~ 5.3	4.5 ~ 7.0	4.0 ~ 8.0
Post Height (mm)	2.0 ~ 10.0	2.0 ~ 7.0	3.0 ~ 9.0
Material	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)
Sterilization	Radiation Sterilization	Radiation Sterilization	Radiation Sterilization
S.E	The subject device has the same intended use, design, and technological characteristics as the primary predicate device (k123155, k160106). The diameter of the new model is smaller than the primary predicate device. We identified a reference device which has the diameter size (4mm). The post height is slightly higher than the reference device, however, this minor difference does not raise a question in substantial equivalence since the user can select an appropriate height model according to each patient need.		

Device Name	**Subject Device**	**Primary Predicate Device**
Manufacturer	SHINHUNG MST CO., LTD.	SHINHUNG MST CO., LTD.
Device Name	Duo Abutment	Duo Abutment
Design		
510(k) Number	K223395	K123155
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 for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.	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.
Diameter (mm)	4.6 ~ 5.1	4.6 ~ 6.1
Gingiva Height (mm)	1.0 ~ 5.0	1.0 ~ 5.0
Post Height (mm)	7.0	4.0 ~ 7.0

Material	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)
Sterilization	User Sterilization	User Sterilization
S.E.	The subject device has the same intended use, design, and technological characteristics as the primary predicate device (k123155). The modification is only for adding a few more size options within the same range.	

Device Name	**Subject Device**	**Primary Predicate Device**	**Reference Device**
Manufacturer	SHINHUNG MST CO., LTD.	Osstem Implant Co., Ltd.	SHINHUNG MST CO., LTD.
Device Name	Duo Plus Abutment	Transfer Abutment	Duo Abutment
Design			
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 for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.	The ET/SS 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 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.	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.
510(k) Number	K223395	K120847	K123155
Diameter (mm)	4.1 ~ 6.1	4.0 ~ 7.0	4.6 ~ 6.1
Gingiva Height (mm)	1.0 ~ 5.0	1.0 ~ 5.0	1.0 ~ 5.0
Material	Pure Titanium Gr 4 (ASTM F67)	Titanium Alloy Ti-6Al-4V (ASTM F136)	Pure Titanium Gr 4 (ASTM F67)
Sterilization	User Sterilization	User Sterilization	User Sterilization
S.E.	The subject device has the same intended use, design, and technological characteristics as the primary predicate device (k120847). The only difference would be area of TiN coating, but this difference does not raise a question in substantial equivalence.		

Device Name	Subject Device	Primary Predicate Device	Reference Device
Manufacturer	SHINHUNG MST CO., LTD.	SHINHUNG MST CO., LTD.	Nobel Biocare AB
Device Name	Temporary Abutment	Temporary Abutment	Temporary Snap Abutment
Design			
510(k) Number	K223395	K123155	K161435
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 for delayed loading and immediate loading is possible when good primary stability is achieved and with appropriate occlusal loading.	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 Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (180) days.
Diameter (mm)	4.6 ~ 5.1	4.1 ~ 4.6	4.0 ~ 6.0
Gingiva Height (mm)	2.0 ~ 3.0	1.0 ~ 3.0	1.5 ~ 3.0
Material	Pure Titanium Gr 4 (ASTM F67)	Pure Titanium Gr 4 (ASTM F67)	Titanium vanadium alloy (ASTM F136)
Sterilization	User sterile	User sterile	User sterile
S.E	The subject device has the same intended use, design, and technological characteristics as the primary predicate device (k123155). The only difference is that the diameter of the new models is outside of the range. We identified a reference device which cover the diameter range of the subject device.		

Substantial Equivalence Discussion

The Luna Dental Implant System (Healing Abutment, Duo Abutment, Duo Plus Abutment, and Temporary Abutment) are substantially equivalent to its predicate device (k123155) in terms of indications for use, raw material, and design. The wording of the indications for use statement is slightly different but that does not affect the intended use.

The difference is in size range. 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.

8. Non-Clinical Testing

Risk analysis and validation activities were performed according to the ISO 14971 and the result support that the predicate device does not raise a new question in safety and performance.

A non-clinical worst-case MRI review was conducted to evaluate the Luna Implant System device in an MRI environment using scientific evidence 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 49.2 (2019): 783-795). Titanium Grade 4 and Titanium alloy (Ti-6Al-4V, ELI) were assessed according to magnetic induction displacement force (ASTM F2052), magnetic induction torque (ASTM F2213), RF induction heating (ASTM F2182), and image artifact (ASTM F2119) by T. O. Woods et al. Based on that rationale, we have addressed parameters per FDA guidance " Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetic induced displacement force and torque.

The following test items were previously submitted and reviewed under K123155.

- Sterilization – Radiation and Moist Heat
- Shelf life for sterile devices
- Biocompatibility

9. Conclusion

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

Based on the similarities, we conclude that the Luna Dental Implant System is substantially equivalent to the predicate devices.