January 13, 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: K221317
Trade/Device Name: S-Mono
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 13, 2022
Received: December 15, 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)*
K221317

Device Name
S-Mono

Indications for Use *(Describe)*
The S-Mono is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. S-Mono is intended for single use only. It is intended for delayed 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

(K221317)

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

Date: 1/12/2023

1. Submitter

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: S-Mono
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: DZE, NHA
- Classification regulation: 21CFR 872.3640

4. Predicate Device:

- Primary Predicate:
  MS SYSTEM by OSSTEM Implant Co., Ltd. (K083067)
- Reference Devices:
  MS SA IMPLANT SYSTEM by OSSTEM Implant Co., Ltd. (K122171)
  MS System (Narrow Ridge) by OSSTEM Implant Co., Ltd. (K080594)

5. Description:

The S-Mono is made of Titanium Alloy (ASTM F136) as the raw material. This device supports dental prosthesis such as an artificial tooth by surgically implanting it in the alveolar bone of the mandibular anterior region with a narrow tooth gap, and is intended to restore the patient's chewing function. It is one-body type which includes fixture and abutment. The surface of the fixture is treated using RBM (Resorbable Blast Media). It is roughened by blasting with hydroxyapatite powder and then pickling with nitric acid. The Temporary Cap is made of POM (Polyoxy Methylene) and intended to relieve the patient's foreign body sensation and protect the abutment part while the dental prosthesis is being manufactured. This cap is placed over the abutment part and is used temporarily before the dental prosthesis is placed. The material, dimension, and intended use of the subject devices are similar to devices currently marketed worldwide.

6. Indication for use:

The S-Mono is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. S-Mono is intended for single use only. It is intended for delayed loading.

7. Basis for Substantial Equivalence

- Dental Implant System

Device Name	Subject Device	Primary Predicate Device	Reference Predicate Device
Manufacturer	SHINHUNG MST CO., LTD.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
Device Name	S-Mono	MS System (Narrow Ridge)	MS SA IMPLANT SYSTEM (Narrow Ridge)
510(k) Number	K221317	K083067	K122171
Design			
Intended use	The S-Mono is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. S-Mono is intended for single use only. It is intended for	The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially	The MS SA System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS SA System (Narrow Ridge) is

	delayed loading.	edentulous patients. MS System (Narrow Ridge) is intended for single use only. It is not for immediate loading.	intended for single use only. It is intended for delayed loading.
Structure	- R.B.M (Resorbable Blasting Media). - Threaded Body Design - One Body Implant	- R.B.M (Resorbable Blasting Media). - Threaded Body Design - One Body Implant	- SA (Sandblasting and acid etching). - Threaded Body Design - One Body Implant
Thread body Diameter (D)	2.5, 3.0	2.5, 3.0	2.5, 2.9
Length (mm) of thread	8.5, 10.0, 11.5, 13.0	10.0, 11.5, 13.0	8.5, 10.0, 11.5, 13.0
Material	Titanium alloy Ti-6Al-4V (ASTM F136)	Titanium alloy Ti-6Al-4V (ASTM F136)	Titanium alloy Ti-6Al-4V (ASTM F136)
Surface	R.B.M (Resorbable Blasting Media)	R.B.M (Resorbable Blasting Media)	SA (Sandblasting and acid etching)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
S.E.	The S-Mono has the same intended use, material, and technological characteristics as the predicate device. There is a difference in wording between the subject device and the primary predicate device which is “It is not for immediate loading” vs “It is intended for delayed loading”. However, the revision in wording does not change the device indications. There might be some other differences in design, however, the differences are minor and do not raise a question in safety and performance for its intended use. Based on the information provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.		

▪ Temporary Cap

Device Name	**Subject Device**	**Predicate Device**
Manufacturer	SHINHUNG MST CO., LTD.	OSSTEM Implant Co., Ltd.
Device Name	S-Mono	MS System (Narrow Ridge)
Design		
510(k) Number	K221317	K080594
Intended use	The S-Mono is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. S-Mono is intended for single use only. It is not for immediate loading.	The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) are intended for single use only and not for immediate loading.

Structure	One-touch locking design	One-touch locking design
Material	POM (Polyoxy Methylene) ASTM 1855	POM (Polyoxy Methylene) ASTM 1855
Sterilization	User sterile	User sterile
S.E.	The S-Mono has the same intended use, material, and technological characteristics as the predicate device. There might be some differences in design, however, the differences are minor and do not raise a question in safety and performance for its intended use. Based on the information provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.	

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137 for gamma sterilization and ISO 11737, ISO 17665-1, and ISO 17665-2 for steam sterilization.
- Shelf-life testing has been performed in according with ASTM F1980, ASTM F1929, and ISO 11737-2.
- EDS (Energy-dispersive X-ray spectroscopy), SEM Analysis, and Surface Roughness Analysis were performed to evaluate the fixture surface characteristics after RBM treatment.
- Biocompatibility Tests were performed in accordance with ISO 10993-1, 3, 5, 6, 10, 11, 12, and 33.
- MR Conditional labeling
  A non-clinical worst-case MRI review was conducted to evaluate the S-Mono 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 alloy (Ti-6Al-4V, ELI) was 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.

9. Conclusion

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

Overall, the S-Mono has the following similarities to the predicate device:

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

Based on the similarities, we conclude that the S-Mono is substantially equivalent to the predicate devices.