July 2, 2021

Osstem Implant Co., Ltd.
% Peter Lee
RA/QA Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K210097
Trade/Device Name: Estar-Z
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 3, 2021
Received: June 4, 2021

Dear Peter 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 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,

Michael E. Adjodha, M.ChE.
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)*
K210097

Device Name
Estar-Z

Indications for Use *(Describe)*
Estar-Z is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges.

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.

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510(k) Summary

K210097

Date: June 03, 2021

1. Company and Correspondent making the submission

- Submitter's Name : Osstem Implant Co., Ltd.
- Address : A-dong, 51, Mayu-ro 238beon-gil, Siheung-Si Gyeonggi-do, 15079, Republic of Korea
- Contact : Ms. Jungmin Yoo
- Phone : +82-70-4394-7896

- Correspondent's Name : Hiossen Inc.
- Address : 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact : Mr. Peter Lee
- Phone : +1-267-759-7031

2. Proposed Device

- Trade or (Proprietary) Name : Estar-Z
- Classification Name : Porcelain powder for clinical use
- Regulation Number : 21 CFR 872.6660
- Devce Classification : Class II
- Classification Product Code : EIH

3. Predicated Device(s)

- Primary Predicate
  LUXEN Zr, LUXEN Smile, DENTALMAX Co., Ltd. (K171785)

4. Description

Estar-Z is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges.

Estar-Z is prefabricated ceramic block (pre-sintered yttrium-stabilized zirconium oxide) which is to be milled and sintered in the furnace to produce the final dental restorations. After sintering, it forms polycrytstalline oxide ceramic consisted of Tetragonal Zirconium Oxide Polycrystal (TZP).

Estar-Z is provided in three types as Estar-Z T, Estar-Z HT, and Estar-Z ST. In accordance with ISO 6872:2015, Estar-Z T and Estar-Z HT are classified as Type II Class 5 zirconia and Estar-Z ST is classified as Type II Class 4b zirconia.

Estar-Z is provided in non-sterile and available in various shades and thickness of disk shape (Ø98mm) as follows:

Estar-Z T	
Shade	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, D2, D3, D4
Thickness (mm)	10, 12, 14, 16, 18, 20, 22, 25

Estar-Z HT	
Shade	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, Z4 Multi A1, Multi A2, Multi A3, Multi A3.5, Multi A4, Multi B1, Multi B2, Multi B3, Multi B4, Multi C1, Multi C2, Multi C3, Multi C4, Multi D2, Multi D3, Multi D4
	*Shade with 'Multi': Multi-layered zirconia has color gradation similar to the color of natural teeth.
Thickness (mm)	10, 12, 14, 16, 18, 20, 22, 25

Estar-Z ST	
Shade	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, D2, D3, D4
Thickness (mm)	10, 12, 14, 16, 18, 20, 22, 25

5. Substantial Equivalent Comparison

	Proposed Device	Predicate Device	Comparison
Device Name	Estar-Z T Estar-Z HT	LUXEN Zr	Different
510(k) Number	K210097	K171585	Different
Manufacturer	Osstem Implant Co., Ltd.	DENTALMAX Co., Ltd.	Different
Regulation Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
Regulation Number	872.6660	872.6660	Same
Product Code	EIH	EIH	Same
Device Class	II	II	Same
Indications for Use	Estar-Z is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges.	LUXEN Zr is indicated for the production of all-ceramic inlays, multi-units bridges, onlays, and veneers without zirconium dioxide frameworks.	Similar
Principle of Operations	This partial sintered zirconia block is milled and finally sintered to make dental prosthesis.	This partial sintered zirconia block is milled and finally sintered to make dental prosthesis.	Same

Physical Properties				
	Standard Conformed	ISO 6872:2015	ISO 6872:2015	Same
	Classification	Type II Class 5	Type II Class 5	Same
	Flexural Strength	>800 MPa	1038 ± 135 MPa	Similar
	Delivery Form(s)	Disk type	Disk type	Same
	Thickness	10, 12, 14, 16, 18, 20, 22, 25mm	10, 12, 14, 16, 18, 20, 22, 25mm	Same
	Shade(s)	Estar-Z T: A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, D2, D3, D4 Estar-Z HT: A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, Z4, Multi A1, Multi A2, Multi A3, Multi A3.5, Multi A4, Multi B1, Multi B2, Multi B3, Multi B4, Multi C1, Multi C2, Multi C3, Multi C4, Multi D2, Multi D3, Multi D4	A0, A1, A2, A3, B1, B2, B3, B4, C4, B1-B2-B3-B4 LAYER	Different
	Sterile	Non-sterile	Non-sterile	Same
Biocompatibility Evaluation				
	Standard Conformed	ISO 10993-1 and ISO 7405	ISO 10993-1	Similar
	Classification	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Same

	Proposed Device	Predicate Device	Comparison
Device Name	Estar-Z ST	LUXEN Smile	Different
510(k) Number	K210097	K171585	Different
Manufacturer	Osstem Implant Co., Ltd.	DENTALMAX Co., Ltd.	Different
Regulation Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
Regulation Number	872.6660	872.6660	Same
Product Code	EIH	EIH	Same
Device Class	II	II	Same
Indications for Use	Estar-Z is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges.	LUXEN Zr is indicated for the production of all-ceramic inlays, multi-units bridges, onlays, and veneers without zirconium dioxide frameworks.	Similar

Principle of Operations		This partial sintered zirconia block is milled and finally sintered to make dental prosthesis.	This partial sintered zirconia block is milled and finally sintered to make dental prosthesis.	Same
Physical Properties				
	Standard Conformed	ISO 6872:2015	ISO 6872:2015	Same
	Classification	Type II Class 4b	Type II Class 4b	Same
	Flexural Strength	>500 MPa	770 ± 66 MPa	Similar
	Delivery Form(s)	Disk type	Disk type	Same
	Thickness	10, 12, 14, 16, 18, 20, 22, 25mm	10, 12, 14, 16, 18, 20, 22, 25mm	Same
	Shade(s)	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, D2, D3, D4	A0, A1, A2, A3, B1, B2, B3, B4, C4, A1-A2-B3-B4 LAYER B1-B2-B3-B4 LAYER	Different
	Sterile	Non-sterile	Non-sterile	Same
Biocompatibility Evaluation				
	Standard Conformed	ISO 10993-1 and ISO 7405	ISO 10993-1	Similar
	Classification	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Same

6. Indications for Use

Estar-Z is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges.

7. Summary of Non-clinical Performance Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence following FDA recognized standards:

- *ISO 6872:2015, Dentistry - Ceramic materials*
- *ISO 7405:2018, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*
- *ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- *ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- *ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
- *ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*

- *ISO 10993-14:2001, Biological evaluation of medical devices - Part 14: Identification and qualification of degradation products from ceramics*
- *ISO 13356:2015, Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*
- *ISO 14971:2007, Medical devices - Application of risk management to medical devices*

Biocompatibility Evaluation

Biocompatibility evaluation of proposed Estar- Z was considered followed 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," ISO 7405* and the *ISO 10993* suite of standards. The biocompatibility for the proposed device was found to be substantially equivalent to the predicate devices as a result.

Sterilization Validation and Shelf-life

Proposed Estar-Z is delivered in non-sterile status and this device is unnecessary of sterilization prior to use. Therefore, sterilization validation was not considered.

Mechanical Properties

Proposed Estar-Z has been designed and tested in accordance with *ISO 6872 Dentistry - Ceramic Materials* and *ISO 13356 Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*. All tests have passed the evaluation criteria and met the requirement of product-specific ISO 6872 specifies for Class 4b and Class 5 dental ceramics. The mechanical properties were found to be substantially equivalent to the predicate devices as a result.

8. Summary of Clinical Testing

No clinical studies are submitted.

9. Conclusion

The conclusions drawn from the nonclinical and clinical tests that demonstrate that Estar-Z is as safe, as effective, and performs as well as the legally marketed predicate device.