November 20, 2024

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

Re: K242521
Trade/Device Name: Estar-ZE
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: July 25, 2024
Received: August 23, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242521

Device Name

Estar-ZE

Indications for Use *(Describe)*

Estar-ZE 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.

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."

Osstem Implant Co., Ltd.
A-dong, 51, Mayu-ro 238beon-gil, Siheung-si, Gyeonggi-do 15079 Korea
Tel: +82 70 4394 7896 Fax: +82 31 498 0824 www.osstem.com

510(k) Summary

K242521

Date: November 12, 2024

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 Korea, Republic of Korea
- Contact	:	Ms. Seungju Kang
- Phone	:	+82-70-4871-0203
- 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^{E}
- Classification Name	:	Powder, Porcelain
- Regulation Number	:	21 CFR 872.6660
- Device Classification	:	Class II
- Classification Product Code	:	EIH

3. Predicate Device(s)

Primary Predicate

- Trade or (Proprietary) Name	:	Estar-Z (K210097)
- Classification Name	:	Powder, Porcelain
- Regulation Number	:	21 CFR 872.6660
- Device Classification	:	Class II
- Classification Product Code	:	EIH

4. Description

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

Estar-Z^{E} 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). In accordance with ISO 6872:2015, it is classified as Type II Class 5 zirconia.

Estar-Z^{E} is provided in non-sterile and available in various shades and thickness of disk shape and block shape

5. Substantial Equivalence Matrix

	Subject Device	Primary Predicate	Comparison
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	-

Device Name	Estar-Z^E	Estar-Z HT	Different
510(k) Number	K242521	K210097	-
Regulation Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	Same
Product Code	EIH	EIH	Same
Device Class	II	II	Same
Indications for Use	Estar- Z^E is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges	Estar-Z is a ceramic intended to manufacture dental restorations, including inlays, artificial teeth, crowns and bridges	Same
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
Materials composition	Zirconium dioxide Ferric Oxide Erbium(III) oxide Manganese(II) oxide Holder: Stainless Steel, Aluminum Alloy	Zirconium dioxide Iron(III) oxide Erbium(III) oxide Cobalt(II,III) oxide	Different
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	>800 MPa	Same
Delivery Form(s)	Disk type Block type	Disk type	Different
Geometry	· Ø 98 mm disc in different heights from 10 – 30 mm · Height 13 – 40 block in different length from 14 – 85 mm	Ø98 mm disc in different heights from 10 – 25 mm	Different

	Shade(s)	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, S4, Gradation A1, Gradation A2, Gradation A3, Gradation A3.5, Gradation A4, Gradation B1, Gradation B2, Gradation B3, Gradation B4, Gradation C1, Gradation C2, Gradation C3, Gradation C4, Gradation D2, Gradation D3, Gradation D4	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	Different
	Sterile	Non sterile	Non sterile	Same
Substantial Equivalence		**Similarities** The subject device has the same indications for use, principle of operations, manufacturer, and manufacturing process etc. In addition, the subject device is classified in the same Type II Class 5 as its precated Estar-Z HT according to the ISO 6872, and both products meet the requirements from ISO 6872 standard. **Differences** The material composition is different from that of primary predicate due to the difference in the type of coloring additives. However, zirconia powder, the main raw material that makes up most of the subject device, is the same, and we conducted biocompatibility tests of subject device for differences in coloring additives. According to the test results, the subject device meets the requirements from ISO 10993 standards. The delivery forms differ from primary predicate due to differences in the way it is combined with the milling machine and how it is stored and managed after use. However, since the disk type and block type have the same raw material, principle of operations, intended use, manufacturing process, etc., the performance of disk type and block type is same, and we conducted performance test of disk type of subject device. The subject device has a different geometry and shades from primary predicate for variety of products, but we demonstrate substantial equivalence through performance test and biocompatibility test of subject device. ∴Therefore, the Estar-Z^{E} is substantially equivalent previously cleared primary predicate.		

6. Indications for Use

Estar-Z^{E} 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.

Biocompatibility Evaluation

The biocompoatibility testing 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,"* 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.

Mechanical Properties

Proposed Estar-Z^E 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 5 dental ceramics. The mechanical properties were found to be substantially equivalent to the predicate devices as a result.

Sterilization Validation and Shelf-life

Proposed Estar-Z Multi is delivered in non-sterile. Therefore, sterilization validation and shelf-life testing was not considered.

8. Summary of Clnical Testing

No clinical studies are submitted.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Osstem Implant Co., Ltd. concludes that the Estar-Z^E is substantially equivalent to the predicated device as herein.