SEUM Medi Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc
18881 Von Karman Ave. STE 160
Irvine, California 92612

July 28, 2025

Re: K241183
Trade/Device Name: ISO Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 19, 2025
Received: June 27, 2025

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 (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,

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K241183

Device Name
ISO Abutment

Indications for Use *(Describe)*

The ISO Abutment is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla. The ISO Abutment is compatible with the following fixtures.

ISO Abutment	Fixture Description	Body Diameter	Manufacturer	510(k) Number
SMSOT351 ~ SMSOT356 SMSOT351H ~ SMSOT356H	Osstem_TSIII_SA Implant	Ø 3.75, 3.77	Osstem Implant Co., Ltd.	K121995
SMSOT401 ~ SMSOT406 SMSOT401H ~ SMSOT406H		Ø 4.2, 4.25, 4.63, 4.65, 5.05, 5.08		
SMSAA401 ~ SMSAA406 SMSAA401H ~ SMSAA406H	Medimecca Chaorum_PSF Model Series_NP	Ø 3.75	Medimecca Co.,Ltd.	K160536
SMSAS401 ~ SMSAS406 SMSAS401H ~ SMSAS406H	Dentium_Superline	Ø 3.6, 4.0, 4.5, 5.0, 6.0, 7.0	Dentium Co., Ltd.	K160965
SMSZP351 ~ SMSZP356 SMSZP351H ~ SMSZP356H	Biohorizons_Tapered Internal Implant, Mountless, RBT_3.8	Ø3.8	BioHorizons Implant Systems, Inc.	K071638
SMSNA301 ~ SMSNA306 SMSNA301H ~ SMSNA306H	Surgikor Fixation_NP	Ø3.0	Surgikor LLC	K182615
SMSNA351 ~ SMSNA356 SMSNA351H ~ SMSNA356H	Surgikor Fixation_RP	Ø3.5, 3.9		
SMSNA431 ~ SMSNA436 SMSNA431H ~ SMSNA436H	Surgikor Fixation_WP	Ø4.3, 5.0		
SMSMAR401 ~ SMSMAR406 SMSMAR401H ~ SMSMAR406H	Megagen_Xpeed AnyRidge Internal Fixture	Ø4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	Megagen Implant Co., Ltd.	K140091
SMSDQ301 ~ SMSDQ306 SMSDQ301H ~ SMSDQ306H	Dentis_s-Clean One-Q-SL_Narrow	Ø3.0, 3.3	DENTIS CO., LTD.	K161244
SMEBM331 ~ SMEBM336 SMEBM331H ~	Osstem_USIII_SA	Ø3.75	Osstem Implant Co., Ltd.	K161103

SMEBM336H				
SMEBM401 ~ SMEBM406 SMEBM401H ~ SMEBM406H		Ø4.23, 4.27, 4.65		
MEBM501 ~ SMEBM506 SMEBM501H ~ SMEBM506H		Ø5.05, 5.1		
SMETW501 ~ SMETW506 SMETW501H ~ SMETW506H		Ø5.05, 5.1, 5.13		
SMSTC331 ~ SMSTC336 SMSTC331H ~ SMSTC336H	3I Osseotite Certain Dental Implant_3.4	Ø 3.25	Implant Innovation, INC.	K063341
SMSTC401 ~ SMSTC406 SMSTC401H ~ SMSTC406H	3I Osseotite Certain Dental Implant _4.1	Ø 4.0		
SMITT401 ~ SMITT406 SMITT401H ~ SMITT406H	Neobiotech IT III_Active	Ø4.0	Neobiotech Co., Ltd.	K181137
SMITB331 ~ SMITB336 SMITB331H ~ SMITB336H	Straumann Bone Level_NC	Ø3.3	STRAUMANN USA, LLC	K150938
SMITB401 ~ SMITB406 SMITB401H ~ SMITB406H	Straumann Bone Level_RC	Ø4.1		

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(K241183)

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

Date: July 28, 2025

1. 510k Submitter:

SEUM Medi Co., Ltd.
2F, 95, Baekbeom-ro, Namdong-gu, Incheon, Republic of Korea, 21540

Tel: +82-32-321-7306

2. Device:

Trade name: ISO Abutment
Common name: Dental implant abutment
Classification name: Endosseous dental implant abutment, 21CFR 872.3630
Product code: NHA

3. Predicate Devices:

Primary predicate device -
Kerator, K112787 (Product Code: NHA, 21CFR 872.3630) by KJ Meditech Co., Ltd.
Reference devices -
K121995, K160536, K160965, K071638, K182615, K140091, K161244, K161103, K063341, K181137, K150938

4. Description:

The ISO Abutment is to be placed into the dental implant to provide support for a prosthetic restoration. The ISO Abutment is made from Titanium grade Ti-6AI-4V ELI (meets ASTM Standard F-136) and compatible with several fixtures made by 3rd party implant manufactures.

5. Indication for use:

The ISO Abutment is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla. The ISO Abutment is compatible with the following fixtures.

ISO Abutment	Fixture Description	Body Diameter	Manufacturer	510(k) Number

SMSOT351 ~ SMSOT356 SMSOT351H ~ SMSOT356H	Osstem_TSIII_SA Implant	Ø 3.75, 3.77	Osstem Implant Co., Ltd.	K121995
SMSOT401 ~ SMSOT406 SMSOT401H ~ SMSOT406H		Ø 4.2, 4.25, 4.63, 4.65, 5.05, 5.08, ,		
SMSAA401 ~ SMSAA406 SMSAA401H ~ SMSAA406H	Medimecca Chaorum_PSF Model Series_NP	Ø 3.75	Medimecca Co.,Ltd.	K160536
SMSAS401 ~ SMSAS406 SMSAS401H ~ SMSAS406H	Dentium_Superline	Ø 3.6, 4.0, 4.5, 5.0, 6.0, 7.0	Dentium Co., Ltd.	K160965
SMSZP351 ~ SMSZP356 SMSZP351H ~ SMSZP356H	Biohorizons_Tapered Internal Implant, Mountless, RBT_3.8	Ø3.8	BioHorizons Implant Systems, Inc.	K071638
SMSNA301 ~ SMSNA306 SMSNA301H ~ SMSNA306H	Surgikor Fixation_NP	Ø3.0	Surgikor LLC	K182615
SMSNA351 ~ SMSNA356 SMSNA351H ~ SMSNA356H	Surgikor Fixation_RP	Ø3.5, 3.9		
SMSNA431 ~ SMSNA436 SMSNA431H ~ SMSNA436H	Surgikor Fixation_WP	Ø4.3, 5.0		
SMSMAR401 ~ SMSMAR406 SMSMAR401H ~ SMSMAR406H	Megagen_Xpeed AnyRidge Internal Fixture	Ø4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	Megagen Implant Co., Ltd.	K140091
SMSDQ301 ~ SMSDQ306 SMSDQ301H ~ SMSDQ306H	Dentis_s-Clean One-Q-SL_Narrow	Ø3.0, 3.3	DENTIS CO., LTD.	K161244
SMEBM331 ~ SMEBM336 SMEBM331H ~ SMEBM336H	Osstem_USIII_SA	Ø3.75	Osstem Implant Co., Ltd.	K161103
SMEBM401 ~ SMEBM406 SMEBM401H ~ SMEBM406H		Ø4.23, 4.27, 4.65		
SMEBM501 ~ SMEBM506 SMEBM501H ~ SMEBM506H		Ø5.05, 5.1		
SMETW501 ~ SMETW506 SMETW501H ~ SMETW506H		Ø5.05, 5.1, 5.13		

SMSTC331 ~ SMSTC336 SMSTC331H ~ SMSTC336H	3I Osseotite Certain Dental Implant_3.4	Ø 3.25	Implant Innovation, INC.	K063341
SMSTC401 ~ SMSTC406 SMSTC401H ~ SMSTC406H	3I Osseotite Certain Dental Implant _4.1	Ø 4.0		
SMITT401 ~ SMITT406 SMITT401H ~ SMITT406H	Neobiotech IT III_Active	Ø4.0	Neobiotech Co., Ltd.	K181137
SMITB331 ~ SMITB336 SMITB331H ~ SMITB336H	Straumann Bone Level_NC	Ø3.3	STRAUMANN USA, LLC	K150938
SMITB401 ~ SMITB406 SMITB401H ~ SMITB406H	Straumann Bone Level_RC	Ø4.1		

6. Substantial Equivalence:

Comparison Chart

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>510k Number</td><td>K241183</td><td>K112787</td></tr>
<tr><td>Device Name</td><td>ISO Abutment</td><td>Kerator</td></tr>
<tr><td>Manufacturer</td><td>Zeros Co., Ltd.</td><td>KJ Meditech Co., Ltd.</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td></tr>
<tr><td>Indications for Use</td><td>The ISO Abutment is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla. The ISO Abutment is compatible with the following fixtures.
<table>
<tr><th>ISO Abutment</th><th>Fixture Description</th><th>Body Diameter</th><th>Manufacturer</th><th>510(k) Number</th></tr>
<tr><td>SMSOT351 ~ SMSOT356
SMSOT351H ~ SMSOT356H</td><td rowspan="2">Osstem_TSIII_SA Implant</td><td>Ø 3.75, 3.77</td><td rowspan="2">Osstem Implant Co., Ltd.</td><td rowspan="2">K121995</td></tr>
<tr><td>SMSOT401 ~ SMSOT406
SMSOT401H ~ SMSOT406H</td><td>Ø 4.2, 4.25, 4.63, 4.65, 5.05, 5.08</td></tr>
<tr><td>SMSAA401 ~ SMSAA406
SMSAA401H ~ SMSAA406H</td><td>Medimecca Chaorum_PSF Model Series_NP</td><td>Ø 3.75</td><td>Medimecca Co.,Ltd.</td><td>K160536</td></tr>
<tr><td>SMSAS401 ~ SMSAS406
SMSAS401H ~ SMSAS406H</td><td>Dentium_Superline</td><td>Ø 3.6, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Dentium Co., Ltd.</td><td>K160965</td></tr>
</table></td><td>The Kerator is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla. The ISO Abutment is compatible with the following fixtures.
<table>
<tr><th>Kerator Model No.</th><th>Fixture Description</th><th>Manufacturer</th></tr>
<tr><td>B331 - B337</td><td>Branemark 3.3 Type</td><td rowspan="3">NOBELPHARMA USA, INC.</td></tr>
<tr><td>B401 - B407</td><td>Branemark 4.0 Type</td></tr>
<tr><td>B501 - B507</td><td>Branemark 5.0 Type</td></tr>
<tr><td>AS351 - AS357</td><td>Astra3.5 Type</td><td rowspan="3">ASTRA TECH AB</td></tr>
<tr><td>AS401 - AS407
G400 - G406</td><td>Astra 4.0 Type</td></tr>
<tr><td>SRS350 - SRS356</td><td>Replace 3.5 Type</td><td rowspan="3">Nobel Biocare USA, Inc.</td></tr>
<tr><td>SRS450 - SRS457</td><td>Replace 4.3 Type</td></tr>
<tr><td>SRS500 - SRS506</td><td>Replace 5.0 Type</td></tr>
<tr><td>BC201 - BC207</td><td>Bicon 2.0(well) Type</td><td rowspan="2">BICON, INC.</td></tr>
<tr><td>BC301 - BC307</td><td>Bicon 3.0(well) Type</td></tr>
<tr><td>PA350 - PA356</td><td>Paragon 3.5 Type</td><td rowspan="2">CORE-VENT BIO-ENGINEERING, INC.</td></tr>
<tr><td>PA450 - PA456</td><td>Paragon 4.5 Type</td></tr>
<tr><td>T401 - T407</td><td>ITI 4.0 Type</td><td>INSTITUT STRAUMANN AG</td></tr>
</table></td></tr>
</table>

	SMSZP351 ~ SMSZP356 SMSZP351H ~ SMSZP356H	Biohorizons_Tapered Internal Implant, Mountless, RBT_3.8	Ø3.8	BioHorizons Implant Systems, Inc.	K071638		
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	SMSNA351 ~ SMSNA356 SMSNA351H ~ SMSNA356H	Surgikor Fixation_RP	Ø3.5, 3.9				
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	SMEBM331 ~ SMEBM336 SMEBM331H ~ SMEBM336H	Osstem_USIII_SA	Ø3.75	Osstem Implant Co., Ltd.	K161103		
	SMEBM401 ~ SMEBM406 SMEBM401H ~ SMEBM406H		Ø4.23, 4.27, 4.65				
	MEBM501 ~ SMEBM506 SMEBM501H ~ SMEBM506H		Ø5.05, 5.1				
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<table>
<tr><td></td><td>
<table>
<tr><td>SMETW501H ~ SMETW506H</td><td></td><td></td><td></td><td></td></tr>
<tr><td>SMSTC331 ~ SMSTC336
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<tr><td>SMSTC401 ~ SMSTC406
SMSTC401H ~ SMSTC406H</td><td>3I Osseotite Certain Dental Implant _4.1</td><td>Ø 4.0</td></tr>
<tr><td>SMITT401 ~ SMITT406
SMITT401H ~ SMITT406H</td><td>Neobiotech IT III_Active</td><td>Ø4.0</td><td>Neobiotech Co., Ltd.</td><td>K181137</td></tr>
<tr><td>SMITB331 ~ SMITB336
SMITB331H ~ SMITB336H</td><td>Straumann Bone Level_NC</td><td>Ø3.3</td><td rowspan="2">STRAUMANN USA, LLC</td><td rowspan="2">K150938</td></tr>
<tr><td>SMITB401 ~ SMITB406
SMITB401H ~ SMITB406H</td><td>Straumann Bone Level_RC</td><td>Ø4.1</td></tr>
</table>
</td><td></td></tr>
<tr><td>Performance Characteristics</td><td>The ISO Abutment is an abutment which is placed into dental implant to provide support for a prosthetic restoration.</td><td>The Kerator is an abutment which is placed into dental implant to provide support for a prosthetic restoration.</td></tr>
<tr><td>Material</td><td>Titanium 6Al 4V ELI Alloy ASTM F136</td><td>Titanium 6Al 4V ELI Alloy ASTM F136</td></tr>
<tr><td>Gingival Height (mm)
Post Height (mm)
Angulation (°)</td><td>
<table>
<tr><th>Gingival Height</th><th>Post Height</th><th>Angulation</th></tr>
<tr><td>1-6mm</td><td>1.5mm</td><td>0</td></tr>
</table>
</td><td>
<table>
<tr><th>Gingival Height</th><th>Post Height</th><th>Angulation</th></tr>
<tr><td>0-8mm</td><td>1.48mm</td><td>0</td></tr>
</table>
</td></tr>
<tr><td>Surface Treatment</td><td>TiN Coating only for the head part of the abutment</td><td>TiN Coating only for the head part of the abutment</td></tr>
</table>

Recommended Sterilization Method	Autoclave	Autoclave

Substantial Equivalence Discussion

The subject device and the predicate device have the same indications and fundamental scientific technology. The subject and predicate device have similar design and employ the same materials, surface treatment, and sterilization method. When compared with predicate devices, no new question of safety or effectiveness has been raised for the subject device. The major difference is that the subject device can be used with more 3rd party manufacturer implants. We have performed reverse engineering analysis and the cross-section validation to verify compatibility, and the results support that the substantial equivalence to the predicate device.

7. Non- clinical Tests

- Sterilization validating testing has been performed in accordance with ISO 17665-1 & 2.
- Biocompatibility test including cytotoxicity test per ISO 10993-5, oral mucosa irritation per ISO 10993-10, skin sensitization per ISO 10993-10, acute systemic toxicity per ISO 10993-11, sub chronic systemic toxicity per 10993-11, bacterial reverse mutation per 10993-3 and ISO 10993-33
- Reverse engineering analysis was conducted on the OEM implant body, OEM abutment, and OEM fixation screw.
- TiN coating tests in accordance with F1044, F1147, and F1160
- 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.

8. Conclusions:

The subject devices and the predicate device have the same intended use and have similar technological characteristics. The substantial equivalence of the different dimensions between the subject device and predicate device is supported by the reference device.

Overall, the ISO Abutment 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 ISO Abutment is substantially equivalent to the predicate devices.