December 5, 2023

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

Re: K232220
Trade/Device Name: SS Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 31, 2023
Received: November 2, 2023

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.

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

510(k) Number *(if known)*
K232220

Device Name
SS Abutment System

Indications for Use *(Describe)*

The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

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
K232220

Date: December 5, 2023

1. Company and Correspondent making the submission

- Submitter's Name : Osstem Implant Co., Ltd.
- Address : 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, 48002, Republic of Korea
- Contact : Ms. Seungju Kang
- Phone : +82-51-850-2500
- 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 : SS Abutment System
- Classification Name : Endosseous dental implant Abutment
- Regulation Number : 21 CFR 872.3630
- Devce Classification : Class II
- Classification Product Code : NHA

3. Predicated and Reference Devices

Primary Predicate	
K160670	US/SS/GS System
Reference Device	
K182091	Osstem Abutment System
K062051	SS System

4. Indication for use

The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

5. Device Description

SS Abutment System is made of titanium, titanium alloy. SS Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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SS Abutment System is similar to other commercially available products based on the intended use, technology used, claims, material composition employed and performance characteristics.

The specifications of the proposed device are as follow;

Device	Content	
ComOcta Plus Abutment	Description	It is used for making general cement-retained/combination prosthesis and used for thick gingiva or deeply placed implant.
	Material	Ti-6Al-4V (ASTM F136), TiN Coating
	Diameter (D) and Length (L)	Ø5.5 x L 5, 6, 7, 7.5, 8, 9.5 Ø6.0 x L 7.5 Ø6.5 x L 5, 6, 7, 8, 8.5, 10 Ø6.8 x L 7.5 Ø7.0 x L 9.5 Ø7.2 x L 8.5 Ø7.6 x L 9.5
ComOcta Milling Abutment	Description	It is used as cement/combination-retained prosthesis and it is used when the abutment's margin shape needs corrections. This device is intended to be modified chairside by the clinician.
	Material	Ti-6Al-4V (ASTM F136)
	Diameter (D) and Length (L)	Ø5.5 x L 14 Ø6.5 x L 14.35
ComOcta Protect Cap	Description	It is made of plastic material and formed with a cover cap to protect porous upper structure.
	Material	POM
	Diameter (D) and Length (L)	Ø5.3 x L 6.35, 7.85, 9.35
Port Abutment	Description	Port Abutment is used for prosthetic restoration. It is for implant retained overdenture at maxilla/mandible in case of the patient has no teeth.
	Material	Ti-6Al-4V (ASTM F136), TiN Coating
	Diameter (D) and Length (L)	Ø6.06 x L 3.5, 4.5, 5.5, 6.5
O-ring Abutment	Description	It is used for overdenture with O-ring attachment.
	Material	Ti-6Al-4V (ASTM F136)
	Diameter (D) and Gingiva Height (G/H)	Ø4.3 x G/H 0, 2, 4
	Material	Titanium Gr 3 (ASTM F67)
	Diameter (D) and Length (L)	Ø4.8 x L 8.2 Ø6.0 x L 8.2
Closing Screw	Description	It is used to protect the exposed platform of the implant during healing period
	Material	Titanium Gr 4 (ASTM F67)

	Diameter (D) and Length (L)	Ø3.5 x L 6.0 Ø4.3 x L 6.4

6. Substantial Equivalence Matrix

These subject devices are cleared in past 510(k); therefore, indication for use, shape, connection structure, material, surface treatment, manufacturer and etc. are the same with predicated devices except dimension of additional products.

	Subject Device	Primary Predicate Device	Remark
Device Name	ComOcta Plus Abutment	ComOcta Plus Abutment	Same
510(k) Number	-	K160670	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Same
Indication for Use	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Same
Principle of Operation	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment	Same
Diameter (D) and Length (L)	Ø5.5 x L 5, 6, 7, 7.5, 8, 9.5 Ø6.0 x L 7.5 Ø6.5 x L 5, 6, 7, 8, 8.5, 10 Ø6.8 x L 7.5 Ø7.0 x L 9.5 Ø7.2 x L 8.5 Ø7.6 x L 9.5	Ø5.5 x L 6.5, 7.5, 8.5, 9.5 Ø6.5 x L 6.5, 7.5, 8.5, 9.5	Different
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
S.E.	**Similarities** Proposed ComOcta Plus Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the predicate ComOcta Plus Abutment, K160670.		

	Differences The diameter Ø5.5 ~ Ø7.6 of proposed device differs from predicate device; but is included in the dimension range of the predicate device, except for the larger diameters Ø6.8 ~ Ø7.6. But they are larger than predicate device, so it is considered to have equal to or greater performance than that of the predicate device. The diameter Ø5.5 and Ø6.5 of proposed device are same and there is only difference in the length 5mm and 6mm which is smaller than the predicate device. However, proposed device has same design, function, connection and platform etc as predicate deivce. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical hoading member always is 11mm according to the ISO 14801, it has same moment arm. As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the predicate device. Therefore, we don't conduct additional fatigue testing. ∴ Proposed ComOcta Plus Abutment and the predicate device have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the predicate device.

	Subject Device	**Predicate Device**	**Remark**
Device Name	ComOcta Milling Abutment	ComOcta Plus Abutment	Different
510(k) Number	-	K160670	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Different
Indication for Use	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Same
Principle of Operation	As general cement retained restoration, it is connected with	As general cement retained restoration, it is connected with	Same

	fixture and cemented crown on the abutment	fixture and cemented crown on the abutment	
Diameter (D) and Length (L)	Ø5.5 x L 14 Ø6.5 x L 14.35	Ø5.5 x L 6.5, 7.5, 8.5, 9.5 Ø6.5 x L 6.5, 7.5, 8.5, 9.5	Different
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
S.E.	**Similarities** Proposed ComOcta Milling Abutment has same function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the predicated ComOcta Plus Abutment, K160670. **Differences** The length 14mm and 14.35mm of proposed device is not included in dimension range of predicate device. However, the diameter range of proposed device is same as predicate device, and since the proposed device is compatible with the same implant as predicate device, it has same design, function, connection and platform etc as predicate deivce. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical hoading member always is 11mm according to the ISO 14801, it has same moment arm. As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the predicate device. Therefore, we don't conduct additional fatigue testing. ∴ The ComOcta Milling Abutment can be modified chairside by hand, to a minimum post height 4mm, and a gingival height between 1mm and 3mm, with no angulation allowed. These dimensions are not significantly different compared to the predicate device and do not present a new worst case for performance testing. In addition, proposed ComOcta Milling Abutment and the predicate ComOcta Plus Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the predicate device.		

	Subject Device	**Predicate Device**	**Remark**
Device Name	ComOcta Protect Cap	ComOcta Retraction Cap	Different
510(k) Number	-	K160670	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same

Design			Different
Indication for Use	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Same
Principle of Operation	ComOcta Protect Cap is temporary connected with ComOcta abutment for minimize foreign body sensation by the patient	ComOcta Retraction Cap is temporary connected with ComOcta abutment for minimize foreign body sensation by the patient and accurate margin impression function when taking impression directly from a ComOcta abutment.	Same
Diameter (D) and Length (L)	Ø5.3 x L 6.35, 7.85, 9.35	Ø6.4 x L 6.25, 7.75, 9.25 Ø7.7 x L 6.1, 7.6, 9.1	Different
Material	POM	POM	Same
	Similarities Proposed ComOcta Protect Cap has same function, indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the predicated ComOcta Retraction Cap, K160670. **Differences** The diameter Ø5.3 of proposed device is smaller than that of predicate device and the length 6.35 ~ 9.35mm of proposed device differs from predicate device. Although there are differences in dimension range and feature, proposed device has same compatible device, ComOcta Abutment, and principle of operation with predicate device. In addition, proposed device is made of POM (Polyoxymethylene) which is same raw material of predicate device. ∴ Proposed ComOcta Protect Cap and the predicated device have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the predicated device.		

	Subject Device	**Reference Device**	**Remark**
Device Name	Port Abutment	Port Abutment	Same

510(k) Number	-	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Same
Indication for Use	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using making implant retained overdenture at maxilla/mandible.	Using making implant retained overdenture at maxilla/mandible.	Same
Diameter (D) and Length (L)	Ø6.06 x L 3.5, 4.5, 5.5, 6.5	Ø4.8 x L 2.5, 3.5, 4.5, 5.5, 6.5	Different
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
S.E.	**Similarities** Proposed Port Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device Port Abutment, K182091. **Differences** The only difference is that the proposed device has a diameter Ø6.06 compared to the reference device diameter Ø4.8. However, added diameter is bigger than reference device and the lengths 3.5~6.5mm is same as the range of reference device. In addition, proposed device is straight type and is not received single load because this is used for making overdenture that means load is dispersed to the full denture. Therefore, we don't consider additional fatigue testing. ∴ Proposed Port Abutment and the predicate device have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the predicate device.		

	Subject Device	**Reference Device**	**Remark**
Device Name	O-ring Abutment	O-ring Abutment	Same
510(k) Number	-	K062051	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same

Design			Same
Indication for Use	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	SS system in 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 terminal or intermediate abutment support for fixed bridgework. SS System is for single stage surgical procedures	Same
Principle of Operation	Using making stud type overdenture prosthetics.	Using making stud type overdenture prosthetics.	Same
Diameter (D) and Gingiva Height (G/H)	Ø4.3 x G/H 0, 2, 4	Ø3.5 x G/H 0, 2, 4	Different
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
S.E.	**Similarities** Proposed O-ring Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference O-ring Abutment, K062051. **Differences** The only difference is that the proposed device has a diameter Ø4.3 compared to the reference device diameter Ø3.5. However, added diameter is bigger than reference device and the gingiva height 0~4mm is same as the range of predicate device. In addition, proposed device is straight type and is not received single load because this is used for making overdenture that means load is dispersed to the full denture. Therefore, we don't consider additional fatigue testing. ∴ Proposed O-ring Abutment and the predicate device have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the predicate device.		

	Subject Device	**Reference Device**	**Remark**
Device Name	Closing Screw	Closing Screw	Same

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510(k) Number	-	K062051	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Different
Indication for Use	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	SS system in 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 terminal or intermediate abutment support for fixed bridgework. SS System is for single stage surgical procedures	Same
Principle of Operation	It is connected with placed implant to protect other substances from ingressing into the fixture after the surgical operation.	It is connected with placed implant to protect other substances from ingressing into the fixture after the surgical operation.	Same
Diameter (D) and Length (L)	Ø3.5 x L 6.0 Ø4.3 x L 6.4	Ø3.5 x L 5.5 Ø4.3 x L 5.85	Different
Material	Titanium Gr 4	Titanium Gr 4	Same
Sterilization	Radiation Sterile	Radiation Sterile	Same
Shelf life	8 years	8 years	Same
S.E.	**Similarities** Proposed Closing Screw has same diameter dimension, design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the predicated Closing Screw, K062051. **Differences** Although there are differences in dimensions that the proposed device is longer than predicate device, it does not affect safety and effectiveness because it is used to protect the exposed platform of the implant during healing period. ∴ Proposed Closing Screw and the predicate device have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.;		

	therefore, the proposed device is substantially equivalent to the predicate device.

7. Summary of Non-clinical Performance Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence.

Biocompatibility Evaluation
Biocompatibility 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,"* The SS Abutment System has same materials, manufacturer, manufacturing process etc., as predicate devices. Therefore, we didn't conduct additional biocompatibility test.

Sterilization Validation and Shelf-life
Validation of the gamma irradiation process was previously conducted for the predicated device. There has been no change to the manufacturing or sterilization processes since then and the subject devices do not present a new worst case for sterilization validation; therefore, additional validation is not required. In addition, SS Abutment System are made with titanium and titanium alloy we don't consider about shelf life of material by itself because this metal is widely known that it generally has no adversely affect by aging. Therefore we certify that product such like metal has no shelf life.

Mechanical Properties
Fatigue testing was considered according to the FDA Guidance Document *Guidance for Industry and FDA Staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment* and ISO 14801 standard with the worst case scenario. The subject devices do not provide a new worst case for fatigue testing because they are all straight.

MR Compatibility
Non-clinical worst-case MRI review was performed to evaluate the Subject device components in the MRI environment using scientific rationale 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), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

8. Summary of Clinical 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 SS Abutment System is substantially equivalent to the predicated devices as herein.