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

September 8, 2022

Re: K221684
Trade/Device Name: Osstem Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 9, 2022
Received: June 10, 2022

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,

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)*
K221684

Device Name
OSSTEM Abutment System

Indications for Use *(Describe)*
The OSSTEM Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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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Osstem Implant Co., Ltd.
66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
Tel: +82 51 850 2500 Fax: +82 51 861 4693 www.osstem.com

510(k) Summary

Date: September 8, 2022

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 : Osstem Abutment System
- Classification Name : Endosseous dental implant abutment
- Regulation Number : 21CFR872.3630
- Devce Classification : Class II
- Classification Product Code : NHA

3. Predicated Device

Primary Predicate

K182091 Osstem Abutment System

Reference Device

K160670 ET US SS Prosthetic System, Osstem Implant Co., Ltd.

4. Indication for use

The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

5. Device Description

Osstem Abutment System is compatible with the following implant systems.

Manufacturer	Model Name	Connection	Diameter (mm)
Osstem Implant Co., Ltd.	TS SA Fixture	Internal Hex	3.2, 3.5, 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.8, 4.9, 5.05, 5.08, 5.1, 5.25, 5.92, 5.95, 6, 6.2, 6.8, 7.1
	US SA Fixture	External Hex	3.6, 4.2, 5.1, 5.2

Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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

Osstem Abutment System is substaintially equivalent in design, function and intended use to the predicate devices as above.

Device	Content	
TS Multi Angled Abutment	Description	TS Multi Angled Abutment is used to adjust the path of prosthesis in the case where the path is misaligned.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.9
	Height (mm)	5, 5.1, 5.5, 5.6, 6, 6.1, 6.5, 6.6, 7.5, 7.6
	Angulation	17°, 30°
US Esthetic-low Abutment	Description	Used in producing screw-retained aesthetic prosthetics. Structure producing prosthetics in cylinder after attaching abutment in the oral cavity. US Esthetic-low Abutment Set is consisted of US Esthetic-low Abutment and Esthetic-low Abutment Screw.
	Material	Titanium (ASTM F67)
	Diameter (mm)	4.8, 5.5
	Height (mm)	2.1, 2.2, 3.0, 3.1, 4.0, 4.1, 5.0, 5.1
US Esthetic-low Abutment Screw	Description	Used to connect US Esthetic-low abutment with fixture.
	Material	Titanium (ASTM F67)
	Diameter (mm)	3.1, 3.6
	Height (mm)	7.8, 7.9, 8.8, 8.9, 9.8, 9.9, 10.8, 10.9
TS Temporary Abutment	Description	TS Temporary Abutment is used for prosthetic restoration. It is used temporarily to maintain

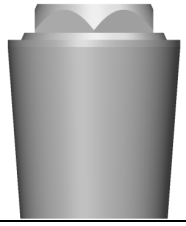
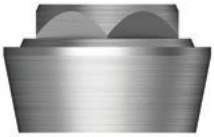
		esthetic appearance until final prosthesis is made.
	Material	Titanium Gr.3 (ASTM F67)
	Diameter (mm)	4.0, 4.5
	G/H (mm)	1.0, 3.0

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.

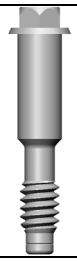
	Proposed Devices	**Predicated Devices**	**Remark**
Device Name	TS Multi Angled Abutment	TS Multi Angled Abutment	Same
510(k) No.	Proposed	K182091	Same
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Design			Same
Indications for Use	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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 screw-retained type prosthesis in multiple cases by using with Esthetic-low cylinder when path adjustment is necessary.	Using making screw-retained type prosthesis in multiple cases by using with Esthetic-low cylinder when path adjustment is necessary.	Same
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Same
Abutment Angle(˚)	17	17, 30	Same
Platform(Ø)	4.9mm	4.9mm	Same
Connection	Hex	Hex	Same
Gingival Height	5.0mm	2.5~4.0mm (17°) 2.5~5.0mm (30°)	5.0mm is added; within the range of the predicates

S.E.	**Similarities** Proposed Multi Angled Abutment has same design, fuction and indication for use; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated Multi Angled Abutment (K182091). **Differences** Proposed Multi Angled Abutment has same diameter, length and angulation that is smaller than predicated Multi Angled Abutment. But the angulation is included in predicated product, and we have already completed the fatigue test for the larger angulation according to the FDA Guidance *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.*Therefore, we didn't conduct additional fatigue testing. ∴ Proposed Multi Angled Abutment and the predicated Multi Angled Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Multi Angled Abutment is substantially equivalent to the predicated Multi Angled Abutment (K182091).

	Proposed Devices	**Predicated Devices**	**Remark**
Device Name	US Esthetic-low Abutment	US Esthetic-low Abutment	Same
510(k) No.	Proposed	K160670	
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Design			Same
Indications for Use	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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	Esthetic-low abutment is connected to implanted fixture and upper part is connected to cylinder Esthetic-low abutment uses cylinder screw to fasten screw-retained type	Esthetic-low abutment is connected to implanted fixture and upper part is connected to cylinder Esthetic-low abutment uses cylinder screw to fasten screw-retained type	Same

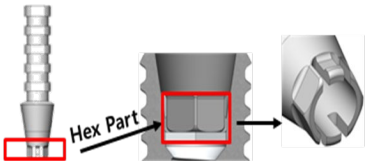
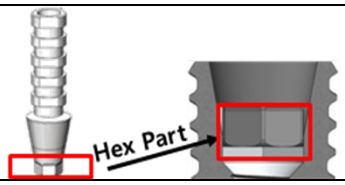
	prosthesis	prosthesis	
Material	Ti CP Gr3 (ASTM F67)	Ti CP Gr3 (ASTM F67)	Same
Diameter(Ø)	2.71mm	2.41mm, 2.71mm, 3.41mm	Same
Length(mm)	5.0mm	1.1~4.1mm	Differnet
Connection	External Hex Connection	External Hex Connection	Same
S.E.	**Similarities** Proposed Esthetic-low Abutment has same design, fuction and indication for use; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated Esthetic-low Abutment (K160670). **Differences** Proposed Esthetic-low Abutment has total length is bigger than predicated Esthetic-low Abutment. In order to consider the fatigue performance of the Esthetic-low Abutment, we take into an account whether the proposed device is chosen as a worst-case compared to predicated device. First of all, to compare the diameter of the compatible implant fixture, we choose the MEM400 as worst case from the predicate devices since it has the smallest diameter and mini connection. Secondly, the diameter of compatible implant fixture to the proposed device, which has regular connection, is 4.20mm and bigger than the diameter of compatible implant fixture to the predicate device, MEM400, which 3.75mm and has mini connection. Also, total length is not affected to choose a worst case because moment arm is not changed. The distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO14801. As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the predicated device. Therefore, we didn't conduct additional fatigue testing. ∴ Proposed Esthetic-low Abutment and the predicated Esthetic-low Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Esthetic-low Abutment is substantially equivalent to the predicated Esthetic-low Abutment (K160670).		

	Proposed Devices	**Predicated Devices**	**Remark**
Device Name	US Esthetic-low Abutment Screw	US Esthetic-low Abutment Screw	Same
510K No.	Proposed	K160670	Same
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	Same

Design			Same
Indication for Use	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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
Principles of Operation	Esthetic-low Abutment Screw is fasten Esthetic-low Abutment to Implanted fixture	Esthetic-low Abutment Screw is fasten Esthetic-low Abutment to Implanted fixture	Same
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Same
Diameter(Ø)	3.1mm	3.1mm, 3.6mm	Same
Length(mm)	11.8mm	7.9~10.8mm	Different
S.E.	**Similarities** Proposed Esthetic-low Abutment Screw has same design, fuction and indication for use; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated Esthetic-low Abutment Screw (K160670). **Differences** Proposed Esthetic-low Abutment Screw has new dimension of total length. ∴ Proposed Esthetic-low Abutment Screw and the predicated Esthetic-low Abutment Screw have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Esthetic-low Abutment Screw is substantially equivalent to the predicated Esthetic-low Abutment Screw (K160670).		

	Proposed Devices	**Predicated Devices**	**Remark**
Device Name	TS Temporary Abutment	TS Temporary Abutment	Same
510K No.	Proposed	K182091	-
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	Same

Osstem Implant Co., Ltd.
66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
Tel: +82 51 850 2500 Fax: +82 51 861 4693 www.osstem.com

Design			Same except for its shape of the hex
Indication for Use	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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 temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Same
Material	Ti CP Gr3 (ASTM F67)	Ti CP Gr3 (ASTM F67)	Same
Diameter(Ø)	4.0, 4.5mm	4.0, 4.5mm	Same
Post Height (mm)	10	10	Same
Hex Size	2.08, 2.48mm	2.08, 2.48mm	Same
Appearance			Different
S.E.	**Similarities** Proposed Temporary Abutment has same design (except for its shape of hex), function and indication for use; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated Temporary Abutment (K182091) **Differences** Shape of the hex between the proposed and predicated Temporary Abutment is different. But the hex size that is connected to fixture is same although there is difference of design of hex compared with predicated product. In addition, since Temporary Abutment is used to make temporary prosthesis for esthetic purpose for healing period after placement of fixture, changing the shape of hex does not affect the any performance. Therefore, we do not need to consider fatigue testing.		

	∴ While shape of the hex of Temporary Abutment is changed compared to the predicates, proposed Temporary Abutment and the predicated Temporary Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Temporary Abutment is substantially equivalent to the predicated Temporary Abutment (K182091).

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 Osstem Abutment System has same materials, manufacturer, manufacturing process etc., as predicate device and reference devce. Therefore, we didn't conduct additional biocompatibility test.

Sterilization Validation and Shelf-life
Proposed devices are provided to the market in non-sterile. The proposed devices are end-user sterilized by moist heat with the same parameters as the primary predicate. The Osstem Abutment System has same materials, manufacturer, manufacturing process etc., as predicate device and reference device. Therefore, we didn't conduct additional sterilization validation.

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. First of all, gingival height of proposed TS Multi Angled Abutment is large than predicate device at the same angle. But the predicate device with the same gingival height has a larger angle. Secondly, proposed US Esthetic-low Abutment which has regular connection has bigger total length than predicate deivce. But predicate device has mini connection and total length is not affected to choose a worst case. Finally, TS Temporary Abutment has same hex size that is connected to implant although there is difference of design of hex compared with predicate device. In addition, TS Temporary Abutment is used temporarily during healing period. Therfore, we didn't conduct additional fatigue test because the proposed device is not worst-case.

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 Osstem Abutment System is substantially equivalent to the predicated devices as herein.