DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2017

Osstem Implant Co., Ltd.
% David Kim
Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K163557
Trade/Device Name: SS SA Fixture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 14, 2017
Received: April 14, 2017

Dear David Kim:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163557

Device Name
SS SA Fixture

Indications for Use *(Describe)*
The Osstem Implant is 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra Wide Fixture System is intended to be used in the molar region.

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

Date: May 11, 2017

1. Company and Correspondent making the submission:

- Submitter's Name:	OSSTEM Implant Co., Ltd.
- Address:	66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
- Contact:	Mr. Hee Kwon Son
- Phone:	+82 51 850 2575
- Correspondent's Name:	HIOSSEN Inc.
- Address:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact:	DAVID KIM
- Phone:	267 759 7031

2. Device:

Trade or (Proprietary) Name : SS SA Fixture
Common or usual name : Dental Implant
Classification Name : Endosseous Dental Implant
Regulation Number : 21CFR872.3640
Device Classification: Class II
Primary Product Code: DZE
Subsequent Product Code: NHA

3. Predicate Device:

Substantial equivalence is claimed to the following devices:
Primary Predicate
K120847, ET/SS Implant System, OSSTEM Implant Co., Ltd.

Reference predicate
K161604, OSSTEM Implant System, OSSTEM Implant Co., Ltd.

4. Description:

The SS SA Fixture is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.

Fixture is made of pure titanium metal and supplied sterile. The surface is SA, Sandblasting and Acid etching, treated.

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

1) SSIII SA Ultra-Wide Fixture

Device Description	Intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is supplied sterile. Only straight type abutments are to be used with the Ultra-Wide Fixture System.	
Material	Pure Titanium (ASTM F 67)	
Surface	SA surface treatment	
	Diameter (mm)	Length (mm)
Dimension	5.96,	6, 8.5
	6.0	7
	5.95	10
	5.92	11.5, 13
	6.93	6
	6.8	7, 8.5, 10, 11.5, 13

- Substantial Equivalence Matrix

	SS SA Fixture (SSIII SA Ultra Wide Fixture)	Primary Predicate ET/SS Implant System (SSII/III SA Fixture)	Reference predicate OSSTEM Implant System	
510(K) No.	New Device	K120847	K161604	
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	Same
Indication for use	The Osstem Implant is 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra Wide Fixture System is intended to be used in the molar region.	ET/SS Implant System is 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations	The Osstem Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Fixture System is intended to be used in the molar region. Products with diameter	Same

		such as crowns, bridges, or overdenture.	of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible	
Surgery type	One stage Surgery	One stage Surgery	One or two stage Surgery	Same
Structure	- Non Submerged Fixture - Self tapping - Internal Octagonal connection - Taper Body	- Non Submerged Fixture - Self tapping - Internal Octagonal connection - Straight/Taper body shape	- Internal Hex-connected - Submerged Fixture - Straight/Taper body shape	Same
Platform (D) (mm)	6	4.8~6.0	N/A	Included in predicate
Body Diameter (D) (mm)	5.92, 5.95, 5.96, 6.0, 6.93, 6.8	4.1~4.9/3.75~5.0	3.2, 3.5, 3.75, 3.77, 4.2, 4.25, 4.4, 4.45, 4.6, 4.63, 4.65, 4.8, 4.9, 5.05, 5.08, 5.1, 5.25, 6.2, 7.1	Included in Reference predicate
Length (mm)	6, 7, 8.5, 10, 11.5, 13	6~15.0	6.2, 7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0	Included in predicate
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Same
Surface	SA	SA	SA	Same
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Same
Shelf life	8years	5years	8years	Same with Reference predicate
S E	Same SS SA Fixture have same connection structure, material, manufacture process (including surface treatment), principles of operation, Technological Characteristics and indication for use with ET/SS Implant System (SSII/III SA Fixture) And length of SS SA Fixture is also included in primary predicate ET/SS Implant System (SSII/III SA Fixture) Different Diameter of SS SA fixture is bigger than primary predicate ET/SS Implant System (SSII/III SA Fixture) but Diameter of SS SA fixture is included in range of reference predicate diameter, OSSTEM Implant System. Therefore SSIII SA Ultra Wide Fixture of SS SA Fixture is substantially equivalent to the predicate devices			

5. Indication for use:

The Osstem Implant is 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 final or temporary abutment support for

fixed bridgework. It is intended for delayed loading. Ultra Wide Fixture System is intended to be used in the molar region.

6. Summary of nonclinical testing

The following nonclinical testing data were provided or relied upon in support of the Substantial equivalence determination.

Biocompatibility

Biocompatibility testing on the SS SA Fixture was previously conducted. As the material of construction and manufacturing processes are the same as the predicate device, ET/SS Implant System, OSSTEM Implant Co., Ltd., K120847 and OSSTEM Implant System, OSSTEM Implant Co., Ltd., K161604.

Therefore, no additional testing is required to support the biological safety of the subject devices.

Sterilization validation

Validation of the gamma irradiation process was previously conducted for the predicate devices, OSSTEM Implant System, OSSTEM Implant Co., Ltd., K161604.

There has been no change to the manufacturing, sterilizer or sterilization processes since then; therefore, additional validation is not required.

Surface treatment characterization testing

SS SA Fixture has SA (Sandblasted and Acid etched surface) surface treatment that is exactly same with the predicate devices, ET/SS Implant System, OSSTEM Implant Co., Ltd., K120847 and OSSTEM Implant System, OSSTEM Implant Co., Ltd., K161604. There has been no change to the manufacturing or surface treatment processes since then; therefore, additional characterization testing is not required.

Bone to Implant Contact (BIC) analysis

BIC analysis is conducted with SS SA Fixture containing implants of lengths less than 7mm. We compared the BIC value and confirmed the substantial equivalence status with the predicate device; ET/SS implant System, OSSTEM Implant Co., Ltd., K120847.

Surface area analysis

Surface area analysis is conducted with SS SA Fixture containing implants of lengths less than 7mm. We compared the surface area and confirmed the substantial equivalence status with the predicate device; ET/SS implant System, OSSTEM Implant Co., Ltd., K120847.

Pullout test

Pullout force test was conducted with SS SA Fixture containing implants of lengths less than 7mm. We compared the pullout force value and confirmed the substantial equivalence status with the predicate device; ET/SS implant System, OSSTEM Implant Co., Ltd., K120847.

Fatigue test

The Fatigue testing was considered according to the "Guidance for industry and FDA staff Class Ⅱ Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" and ISO 14801 Dentistry - Fatigue test for endosseous dental implants with the worst case scenario. SS SA Fixture has bigger diameter than the predicate device, ET/SS Implant System, OSSTEM Implant Co., Ltd., K120847. The result of SS SA Fixture static and dynamic compression – bending test will be higher than this predicate; therefore, we do not consider additional fatigue test.

7. Summary of clinical testing

No clinical studies are submitted.

8. Conclusions

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 SS SA Fixture is substantially equivalent to the predicate devices as described herein.