DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 2, 2017

OSSTEM IMPLANT Co., Ltd.
c/o Mr. David Kim
Manager
HiOSSEN Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K161103
Trade/Device Name: US SA Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 6, 2017
Received: January 6, 2017

Dear Mr. 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 yours,

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

OSSTEM Implant Co., Ltd.
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Indications for Use Statement

Indications for Use

510(k) Number K 161103

Device Name : US SA Implant System

Indication for use : The US SA 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 such as bridges, or overdenture.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date: February 1, 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 :	US SA Implant System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant
Regulation Number:	21CFR872.3640
Regulatory Class:	Class II
Product Code:	DZE, NHA

3. Predicate Device :

- Primary predicate
  HU II / HS II FIXTURE SYSTEM, HiOSSEN Inc, K080387

- Reference predicate
  Multi Angled Abutment, OSSTEM Implant Co., Ltd., K123755
  TS Fixture System, OSSTEM Implant Co., Ltd., K121995
  US.SS.GS System, OSSTEM Implant Co., Ltd., K073247
  3i OSSEOTITE Dental Implants, Implant Innovations, Inc, K063286
  HIOSSEN Implant System, HIOSSEN Inc., K140934

4. Description :

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

The US SA Implant System is substantially equivalent in design, function and intended use to the HU II / HS II Fixture System (K080387) of Osstem Implant Co., Ltd., the TS Fixture System (K121995) of OSSTEM Implant Co., Ltd., the Multi Angled Abutment (K123755) of OSSTEM Implant Co., Ltd. and HIOSSEN Implant System (K140934) of HIOSSEN Inc.

The US Multi Angled Abutment is device made of titanium alloy intended for use as an aid in prosthetic restoration.
The US Multi Angled Abutment is used with Multi Ti Cylinder or US Esthetic Low Cylinder that is predicated by 510(K), K140507 Hiossen Prosthetic system and connected to USII SA Fixture and USIII SA Fixture. The US II SA and US III SA fixtures are only compatible with the straight Cemented Abutment and straight UCLA Temporary Abutment from K073247 and the US Multi Angled Abutment included in this submission.

Item	**Content**	
US II SA Fixture	Description	External Hex-connected Submerged Fixture Straight body shape 3 side cutting edge with self-tapping
	Material	Titanium (ASTM F67)
	Diameter and Length	3.5mm X 8.5, 10, 11.5, 13, 15, 18 mm 4.1mm X 7, 8.5, 10, 11.5, 13, 15, 18 mm 4.45mm X 7, 8.5, 10, 11.5, 13, 15, 18 mm 4.9mm X 7, 8.5, 10, 11.5, 13, 15, 18 mm (wide) 4.9mm X 7, 8.5, 10, 11.5, 13, 15, 18 mm (wide ps)
US III SA Fixture	Description	External Hex-connected Submerged Fixture Taper body shape 3 sided cutting edge with self-tapping
	Material	Titanium (ASTM F67)
	Diameter and Length	3.75mm X 8.5, 10, 11.5, 13 mm 4.23mm X 8.5, 10, 11.5 mm 4.27mm X 7 mm 4.65 mm X7, 8.5, 10, 11.5, 13 mm 5.05mm X 10, 11.5 mm (wide) 5.1mm X 7, 13 mm (wide) 5.13mm X 8.5 mm (wide) 5.05mm X 10, 11.5 mm (wide ps) 5.1mm X 7, 13 mm (wide ps) 5.13mm X 8.5 mm (wide ps)

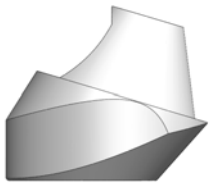
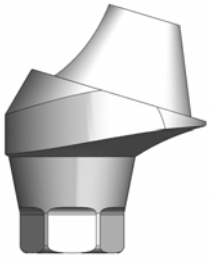
Cover Screw	Description	To be used to protect the exposed platform of the implant during healing period
	Material	Titanium (ASTM F67)
	Diameter	6.4mm, 7.7mm
	Length	5.9mm
US Multi Angled Abutment	Description	US Multi Angle Abutment is used to adjust path of prosthesis for multi-unit restorations.
	Material	Titanium Alloy (ASTM F 136)
	Component	US Multi Angled Abutment Screw.
	Diameter	3.4mm, 4.0mm, 4.1mm
	Angle	17˚, 30˚
Multi Ti Cylinder	Description	Multi Ti Cylinder is used to make final prosthesis using US Multi Angled Abutment
	Material	Titanium Alloy (ASTM F 136)
	Component	Consists of Multi Ti Cylinder Screw.
	Diameter	4.8mm
	Length	7.0mm

- Substantial Equivalence Matrix

	US SA Implant System USII SA Fixture USIII SA Fixture	**Predicate devices**		
		Primary predicate	**Reference predicate**	**Reference predicate**
		HUII / HSII FIXTURE SYSTEM HUII Fixture (K080387)	**TS Fixture System** TSII/III SA Fixture (K121995)	**ET II SA Fixture (**K140934)
Design	 USII USIII		 TSII TSIII	
Intended use	The US SA Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented	The HUII / HSII Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations	The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented	The ETII Fixture 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 such as bridges, or overdenture.	including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HU II / HS II Fixture System is for one and two stage surgical procedures. It is not for immediate load.	retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading	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.
Surgery type	One and two stage Surgery	One and two stage Surgery	One and two stage Surgery	One and two stage Surgery
Structure	- External Hex-connected - Submerged Fixture - Straight / Taper body shape - 3 sided cutting edge with self-tapping	-Submerged Fixture -Body type : Straight Body -Self tapping -Connection : External hex-connected	- Internal Hex-connected - Submerged Fixture - Straight / Taper body shape - 3 sided cutting edge with self-tapping	- Internal Hex-connected - Submerged Fixture - Straight body shape - 3 sided cutting edge with self-tapping
Platform (D)	3.6, 4.2, 5.1, 5.2	3.5~5.1	N/A	N/A
Body Diameter (D)	3.5, 4.1, 4.45, 4.9 3.75, 4.23, 4.27, 4.65, 5.05, 5.1, 5.13	3.5~5.5	TS II SA: 3.5, 4.2, 4.4, 4.9 TS III SA: 3.77, 3.75, 4.25, 4.2, 4.65, 4.63, 4.6, 5.1, 5.08, 5.05,	3.5, 4.2, 4.45, 4.9, 5.0
Length (mm)	7, 8.5, 10, 11.5, 13, 15, 18	7.0~15.0	7.0~15	6.2 ~ 18.2
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA	RBM	SA	SA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	8years	3 years	8 years	8 years
S E	USII SA Fixture and USIII SA Fixture have the same material, indication for use, connection structure as the HUII Fixture in the HU II / HS II Fixture System (K080387) except surface treatment. surface treatment of USII SA Fixture is different from Primary predicate, HUII Fixture but the surface treatment of USII SA Fixture and USIII SA Fixture is the same with surface treatment of TS Fixture System (K121995)			

	And Diameter size and length of US SA Implant System are included dimension range of predicate, HUII Fixture in the HU II / HS II Fixture System (K080387) and ET II SA Fixture **(**K140934) Therefore we state that US SA Implant System is substantially equivalent to the predicate devices as described herein.

	US Multi Angled Abutment	**Predicate devices**	
		Primary predicate	**Reference predicate**
		Multi Angled Abutment	**Cement Abutment**
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
510(k) Number	New	K123755	K073247
Design	 		
Intended use	US Multi Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as bridges, or overdentures.	Multi Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as bridges, or overdentures.	Cement Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Abutment Angle(˚)	17, 30	17, 30	0
platform(Ø)	4.9	4.8	-
connection	External Hex-connected Compatible with USII SA Fixture	Internal Hex-connected Compatible with TSII SA Fixture	External Hex-connected Compatible with USII SA Fixture

Connection	US Multi Angled Abutment has the same material, indication for use, function and similar design as the Multi Angled Abutment (K123755) except connection structure. But connection structure is exactly same with Cement Abutment, K073247 In accordance with difference of connection and shape, we conducted fatigue test to confirm proposed device strength

5. Indication for use :

The US SA 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 such as bridges, or overdenture.

6. Review :

The US SA Implant System has same material and indication for use and similar design and technological characteristics as the predicate device.

7. Summary of nonclinical testing

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence:
Fatigue testing was conducted with subject devices according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment".
Gamma Sterilization Validation was performed with Fixture System according to ISO 11137-1, ISO 11137-2 and ISO 11137-3. Steam sterilization validation was provided according to ISO 17665-1 and ISO 17665-2.
Subject devices are made of the same materials, manufacturing process, chemical composition, and body contact with the predicate devices, the TS Fixture System, OSSTEM Implant Co., Ltd., K121995 and Multi Angled Abutment, OSSTEM Implant Co., Ltd., K123755
therefore US SA Implant System is substantially equivalent to the predicate devices in biocompatibility, surface coating characterization

8. Summary of clinical testing

No clinical studies are submitted

9. 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 US SA Implant System is substantially equivalent to the predicate devices as described herein.