DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 21, 2017

Osstem Implant Co., Ltd.
c/o Mr. David Kim
Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K163088
Trade/Device Name: TSIII BA Fixture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: March 21, 2017
Received: March 21, 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

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Indications for Use Statement

Indications for Use

510(k) Number K163088

Device Name: TSIII BA Fixture

Indication for Use:

TSIII BA Fixture 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.

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: April 18, 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 : TSIII BA Fixture
Common or usual name : Dental Implant
Classification Name : Endosseous Dental Implant
Regulation Number : 21CFR872.3640
Device Classification: Class II
Product Code: DZE

3. Predicate Device:

Primary Predicate
K151626, ETIII Bio-A Fixture System, HIOSSEN Inc.

Reference predicate
K121995, TS Fixture System, OSSTEM Implant Co., Ltd.

4. Device Description:

(1) Design Features (Same with ETIII Bio-SA Fixture System (K151626))
TSIII BA Fixture has features of single threads, internal hex connection, taper body, and BA surface treatment.

(2) Raw material used (Same with ETIII Bio-SA Fixture System (K151626))
TSIII BA Fixture System is permanent dental implant made with Pure Titanium Grade 4 (ASTMF67-06).

(3) BA Surface treatment (Same with ETIII Bio-SA Fixture System (K151626))
The proposed device is sandblasted, acid etched, coated with calcium phosphate by immersing and then finally coated with hydrophilic materials (glucose and NaCl with saline concentrations). Surface treatment of TSIII BA Fixture is exactly same with ETIII Bio-SA Fixture System (K151626) in Surface treatment method and material, etc.

The proposed device, TSIII BA Fixture System is substantially equivalent to commercially and legally available medical devices (ETIII Bio-SA Fixture System (K151626)) based on the intended use, the technology used, the claims, the material used and performance characteristics.

- TSIII BA Fixture

Device Description	Intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is supplied sterile.	
Material	Pure Titanium (ASTM F 67)	
Surface	BA surface treatment	
	Diameter (mm)	Length (mm)
Dimension	3.77	8.5
	3.75	10.0, 11.5, 13.0
	4.25	7.0, 8.5
	4.0	10.0, 11.5, 13.0
	4.65	7.0
	4.63	8.5
	4.6	10.0, 11.5, 13.0
	5.1	6.2, 7.0
	5.08	8.5
	5.05	10.0, 11.5, 13.0

- Substantial Equivalence Matrix

	TSIII BA Fixture	Primary Predicate	Reference predicate	Summary of difference
		ETIII Bio-SA Fixture	TS Fixture System (TSIII SA Fixture & TSIII SA Ultra Wide Fixture)	
510(K) No.	New Device	K151626	K121995	-
Manufacturer	OSSTEM Implant Co., Ltd.	HIOSSEN Inc.	OSSTEM Implant Co., Ltd.	Same with Reference predicate
Indication for use	TSIII BA Fixture is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or	The ETIII Bio-SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support		Indication for use of subject device is almost same with Predicate devices

	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.	of single or multiple –unit restorations including ;cemented retained, screw retained, or over-denture restorations, and terminal or intermediate abut-ment support for fixed bridgework. The ETIII Bio-SA Fixture System is for single and two stage surgical pro-cedures. It is intended for delayed loading.	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 retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. TS Fixture System is compatible with abutment in the ET/SS Implant System.	
Surgery type	One or two stage Surgery	One or two stage Surgery	One or two stage Surgery	Same
Structure	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Taper body Type -Self tapping -Submerged fixture	-Single Thread -Taper body Type -Self tapping -Submerged fixture	Same
Body Diameter (D) (mm)	3.75, 3.77, 4.2, 4.25, 4.6, 4.63, 4.65, 5.05, 5.08, 5.1	3.75, 3.77, 4.25, 4.6 4.65, 4.63, 5.05, 5.08, 5.1	3.75, 3.77, 4.2, 4.25, 4.6, 4.63, 4.65, 5.05, 5.08, 5.1, 6, 5.95, 5.92, 6.8	Same with Reference predicate
Length (mm)	7.0, 8.0, 8.5, 9.5, 10.0, 11.0, 11.5, 12.5, 13.0	7.2 , 8.7, 10.2, 11.7, 13.2, 15.2	7.0, 8.0, 8.5, 9.5, 10.0, 11.0, 11.5, 12.5, 13.0, 15.0,	
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Same

Surface	TSIII BA Fixture is sandblasted, acid etched, coated with calcium phosphate by immersing and then finally coated	ETIII Bio-SA Fixture System is sandblasted, acid etched, coated with calcium phosphate by immersing and	SA (Sandblasting and Acid etching, treated.)	Same with Primary Predicate

	with hydrophilic materials (glucose and NaCl with saline concentrations)	then finally coated with hydrophilic materials (glucose and NaCl with saline concentrations)		
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Same
Shelf life	5years	5years	8years	Same with Primary Predicate
S E	**S.E** Subject devise, TSIII BA Fixture is almost same with Primary Predicate, ETIII Bio-SA Fixture in shape, dimension, intended for use and they have same Technological Characteristics**,** principles of operation, same connection structure and material And subject device and Primary predicate device. Although manufacturer of Primary predicate is different from subject device, all subject device and predicate devices are designed by OSSTEM R&D Center. Therefore, TSIII BA Fixture is substantially equivalent to the predicate devices.			

5. Indication for use

TSIII BA Fixture 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.

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 TSIII BA Fixture was previously conducted. As the material of construction and manufacturing processes are the same as the predicate device, ETIII Bio-SA Fixture (K151626) exactly.

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

Sterilization validation

The sterilization validation of the dental implant (TSIII BA Fixture) was carried out according to the protocol relating to the requirements described in ISO 11137-2:2006.

The substantiated 25 kGy sterilization dose for 10^{-6} SAL is accepted as the bioburden of 1,000 cfu/unit & the verification test performed by the verification dose is met the acceptance criteria. In accordance with ISO11137 VDmax 25, therefore allows use of minimum dose 25 kGy as a routine sterilizing dose.

The results of the evaluation on the material stability show that the packaging materials was

inherently less affected by radiation in the maximum acceptable dose 40 kGy.

The packaging is the same as the predicate. Validation for the packaging was conducted on the TS Fixture System (K121995) according to ASTM F1980 by accelerated aging and validated a 5 year shelf life. No additional shelf-life validation was performed on the subject device.

LAL Testing
LAL testing of the subject device and information per the FDA Guidance Document entitled, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," issued January 21, 2016.

Surface treatment characterization testing
TSIII BA Fixture has BA (sandblasted, acid etched, coated with calcium phosphate by immersing and then finally coated with hydrophilic materials (glucose and NaCl with saline concentrations)) surface treatment that is exactly same with the predicate devices, ETIII Bio-SA Fixture (K151626). There has been no change to the manufacturing or surface treatment processes since then; therefore, additional characterization testing is not required.

Fatigue test
TSIII BA Fixture is exactly same with predicate, TS Fixture System, K121995 in material, shape and dimension except surface treatment. Therefore additional Fatigue testing is not required.

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 TSIII BA Fixture is substantially equivalent to the predicate devices as described herein.