K 121585

OSSTEM IMPLANT
OSSTEM Implant Co., Ltd.
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

JAN 0 7 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April 20, 2012

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804, 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:	Patrick Lim
- Phone:	888 678 0001

2. Device :

Trade or (Proprietary) Name :	TS Implant System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device:

The HGII Short Fixture System, Osstem Implant Co., Ltd, K091678
The ETIII SA Fixture System, HIOSSEN Inc., K101096
The HS/HG Prosthetic System, Osstem Implant Co., Ltd, K100245
The NC Temporary Abutment, STRAUMANN USA, K072679
The RC Temporary Abutment, STRAUMANN USA, K093027

4. Description:
The TS 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.

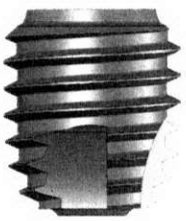
Abutment is device made of titanium alloy and Plastic and it is intended for use to make temporary prosthesis. It consists of Abutment and Abutment Screw.

The TS 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.

Fixture in the TS Implant System is substantially equivalent in design, function and intended use to the HGII Short Fixture System of Osstem Implant Co., Ltd(K091678) and the ETIII SA Fixture System of HIOSSEN Inc.(K101096)

Abutment in the TS Implant System is substantially equivalent in design, function and intended use to the HS/HG Prosthetic System of Osstem Implant Co., Ltd,(K100245) , the NC Temporary Abutment of STRAUMANN USA(K072679) and the RC Temporary Abutment of STRAUMANN USA(K093027)

- Substantial Equivalence Matrix

	TS Implant System	**Predicate devices**	
		HG Ⅱ Short Fixture System (K091678)	**ETⅢ SA Fixture System (K101096)**
Design			
Intended use	The TS 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	The HG Ⅱ Short Fixture System is intended 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. It is not for immediate load.	ETⅢ SA 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 terminal or intermediate abutment support for fixed bridgework. The ETⅢ SA Fixture System is for single and two stage surgical procedures. It is not for immediate load. The Ultra

	as crowns, bridges, or overdenture.		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
Structure	- Internal Hex-connected - Submerged Fixture - Tapered body shape and - cutting edge for self-tapping	- Internal Hex-connected - Submerged Fixture - Straight body shape and - 4 sided cutting edge with self-tapping	- Submerged Fixture - Self tapping - Internal Hexagonal connection - Taper Body
Body Diameter(D)	TSIII SA: 5.1 TSIII SA Ultra Wide: 5.95, 6.8	4.85~6.85	3.5~5.0
Length (mm)	6.2	6.2	7.0~15.0
Material of Fixture	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA	RBM	SA
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf life	8years	5 years	5 years
S. E.	The TS Implant System has the same material, indication for use and similar design as the The HG II Short Fixture (K091678) except surface treatment. but the surface treatment of TS Implant System is the same with surface treatment of ETIII SA Fixture System (K101096)		

5. Indication for use :
The TS 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 crowns, bridges, or overdenture.
TS Implant System is compatible with abutment in the ET/SS Implant System

6. Review :
The TS Implant System has same material and indication for use and similar design and technological characteristics as the predicate device.

The TS Implant System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of clinical testing
No clinical studies are submitted

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

January 7, 2013

Osstem Implant Company, Limited
C/O Mr. Patrick Lim
Hiossen, Incorporated
85 Ben Fairless Drive
FAIRLESS HILLS PA 19030

Re: K121585
Trade/Device Name: TS Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Lim:

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.

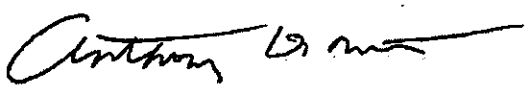
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
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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510(k) Number K 121585

Device Name : TS Implant System

Indication for use : The TS 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 crowns, bridges, or overdenture.

TS Implant System is compatible with abutment in the ET/SS Implant System

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)

Susan Runner DDS, MA 2013.01.04 11:23:44 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: k121585