K130662

JAN 10 2014

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

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: February 26, 2013

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 :	ET Prosthetic System
Common or usual name :	Dental Abutment
Classification Name :	Endosseous dental implant abutment 21CFR872.3630 Class II NHA

3. Predicate Device:
Prosthetic System, K110308, Osstem Implant Co., Ltd
ET/SS Implant System, K120847, Osstem Implant Co., Ltd

4. Description:

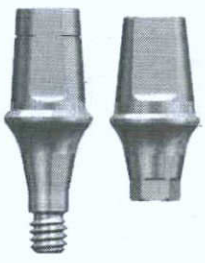
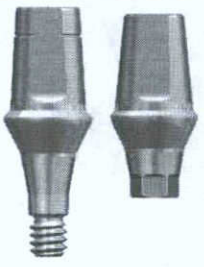
1) The ET Prosthetic System is device made of titanium and titanium alloy intended for use as an aid in prosthetic restoration. It consists of Abutments and Abutment Screws. It's surfaces are partially TiN coated and uncoated.

2) The ET Prosthetic 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.

3) The ET Prosthetic System is substantially equivalent in design, function and intended use to the Prosthetic System(K110308) and ET/SS Implant System (K120847)of Osstem Implant Co., Ltd.

4) These proposed abutments are compatible with the HIOSSEN Implant fixture only. HTIII SA Fixture (K101096)

- Substantial Equivalence Matrix

	ET Prosthetic System	ET/SS Implant System
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
510(k) Number	New	K120847
Design	 **Rigid / Transfer Abutment**	 **Rigid / Transfer Abutment**
Design	 **FreeForm ST Abutment**	 **FreeForm ST Abutment**
Intended use	ET Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Intended for use as an aid in prosthetic rehabilitation.
Material	Titanium Alloy Ti 6Al 4V (ASTM F136)	Titanium Alloy Ti 6Al 4V (ASTM F136)
S E	- Rigid / Transfer Abutment: No changes in function and intended use. Fully the same except G/H Shape. - FreeForm ST Abutment: No changes in function and intended use Fully the same. Art# of diameter 5.0 mm type us added .	

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Part Name	Multi Abutment	Convertible Abutment	Multi Angled Abutment
510K	New	K120847	K110308
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Design			
Type	One body	One body	Two piece (Abutment + Screw)
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Compatible Fixture	HTIII SA Fixture (K101096).	HTIII SA Fixture (K101096).	HTIII SA Fixture (K101096).
Upper Connection Compatible Device	US Esthetic low Cylinders	Convertible Cylinders	US Esthetic low Cylinders
S E	No changes in function and intended use from the predicate device , convertible abutment_K120847. Upper connection part is changed to use cylinder that is used with the predicate device, multi angled abutment_K110308.		

5. Indication for use :
   ET Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

6. Review :
   ET Prosthetic System has same material and indication for use and similar design and technological characteristics as the predicate device.
   Safety tests including biocompatibility have been considered to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing
   The Fatigue testing was conducted 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. The results are in compliance with it and were similar to previously cleared predicate devices."

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 ET Prosthetic System is substantially equivalent to the predicate devices as described herein

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 10, 2014

OSSTEM Implant Company, Limited
C/O Mr. Patrick Lim
Manager
HiOSSEN Incorporated
85 Ben Fairless Drive
Fairless Hills, PA 19030

Re: K130662
Trade/Device Name: ET Prosthetic System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 29, 2013
Received: December 4, 2013

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.

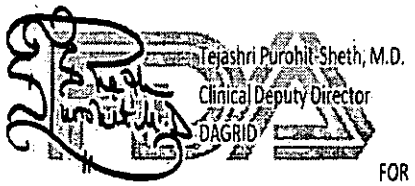
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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,



FOR

Erin I. Keith, M.S.
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

510(k) Number K 130662

Device Name : ET Prosthetic System

Indication for use : ET Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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)

Mary S. Runner -S
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