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

August 20, 2014

OSSTEM IMPLANT Company, Ltd.
C/O Mr. Patrick Lim
Manager
85 Ben Fairless Dr
Fairless Hills, PA 19030

Re: K140507
Trade/Device Name: Hiossen Prosthetic System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 17, 2014
Received: July 23, 2014

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,

Mary S. Runner -S

Erin I. Keith, M.S.
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.
#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

Indications for Use Statement

Indications for Use

510(k) Number K 140507

Device Name : Hiossen Prosthetic system

Indication for use : Hiossen Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

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

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

Date: December 13, 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 :	Hiossen Prosthetic system
Common or usual name :	Dental Abutment
Classification Name :	Endosseous dental implant abutment 21CFR872.3630 Class II NHA

3. Predicate Device:
HU.HS.HG Prosthetic System, OSSTEM Implant Co., Ltd., K081575
TS implant system, OSSTEM Implant Co., Ltd., K121585
NP-cast abutment system, OSSTEM Implant Co., Ltd., K121843
Prosthetic system, OSSTEM Implant Co., Ltd., K110308
US.SS.GS System, OSSTEM Implant Co., Ltd., K073247
TS Fixture system, OSSTEM Implant Co., Ltd., K121995

4. Description :

The Hiossen Prosthetic system is intended for use as an aid in prosthetic restoration. It consists of Abutments, overdenture components and Abutment Screws

The Hiossen 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.

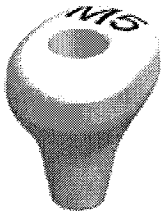
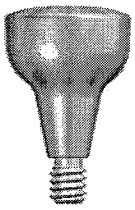
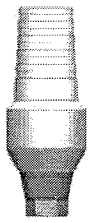
The Hiossen Prosthetic system is substantially equivalent in design, function and intended use to the HU.HS.HG Prosthetic System (K081575), TS implant system (K121585), NP-cast abutment system (K121843), US.SS.GS System, (K073247) and Prosthetic system (K110308)

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

Item	Content	
ET Custom Healing Abutment	Description	Used after successful osseointegration and removing cover screw to make a soft tissue shape before loading prosthetics.
	Material	PEEK
	Diameter	7.05mm/ 5.0mm (Oval in shape)
	Height	7mm, 9mm, 11mm, 7.5mm, 9.5mm, 11.5mm
NP-Cast Abutment	Description	NP-Cast Abutment is used for cases with path and aesthetic and spatial constraints After customization, be sure to use only dental non-precious metal alloy for casting to make the prosthesis
	Material	Co-Cr-Mo Alloy + POM
	Diameter	4.0mm, 4.5mm
	Height	10.5mm, 15.5mm, 13.71mm, 15.71mm, 13mm, 15mm
O-Ring	Description	Use for making stud-type overdenture
	Material	Polymer
	Diameter	4.6mm
O-Ring Retainer Cap set	O-Ring Retainer Cap set consist of Retainer and O-ring Retainer Cap is cleared K81575	
O-Ring Retainer set	O-Ring Retainer set consist of Retainer and O-ring Retainer is cleared K81575	
Esthetic Low Gold Cylinder	Description	Use for making screw-retained prosthesis After customization, be sure to use only dental gold alloy for casting to make the prosthesis
	Material	Gold Alloy + POM
	Diameter	4.8mm
	Height	12mm,

- Substantial Equivalence Matrix

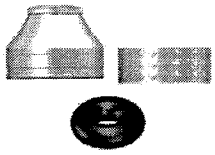
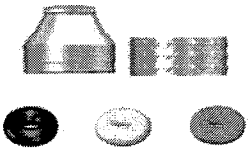
< ET Custom Healing abutment>

Part Name	ET Custom Healing abutment	Predicate devices	
		Healing Abutment	Quick Temporary Abutment
510K	Proposed	K081575	K121585
Material	PEEK	Titanium	PEEK
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
Description (Intended for use)	Used to make a soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.	Used to make a soft tissue shape before setting up prosthetics and removing cover screw after osseointegration	It is used temporary until final prosthesis is made to maintain esthetic Apperance
Indication for use	Hiossen Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	HU/HS/HG Prosthetic System is intended for use as an aid in prosthetic restoration.	The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.
Design			
S E	ET Custom Healing abutment has tha same "Inatended for use" with predicate device, Healing Abutment (K081575) but material is difference Materier of ET Custom Healing abutment is the same with predicate device, Quick Temporary Abutment (K121585)		

< Substantial equivalence of ET Custom Healing Abutment Package>

Package for ET Custom Healing Abutment to keep sterile is Blister & Tyvek package
Package of ET Custom Healing Abutment, has the same material and contact area as package for TS Fixture System that has already been cleared by 510(K), K121995 with shelf life of 8years. Therefore, shelf life of 8years for TS Custom Healing Abutment was submitted

<O-Ring>

Part Name	O-Ring Retainer Cap Set O-Ring Retainer Set O-ring	Predicate devices O-Ring Retainer Cap Set O-Ring Retainer Set O-ring
510K	Proposed	K081575
Material	Retainer: Titanium O-Ring : Acrylonitrile & Butadiene Polymer	Retainer: Titanium O-Ring : Silicone
Manufacturer	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
Intended use	Use for marking stud-type overdenture	Use for marking stud-type overdenture
Design		
S E	O-Ring Retainer Cap, O-Ring Retainer and O-Ring have a cleared with 510(K), K81575 but material of O-ring is changed	

5. Indication for use :
Hiossen prosthetic system is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

6. Review :
Hiossen prosthetic system has same indication for use and technological characteristics as the predicate device.
Hiossen prosthetic system has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been considered to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing
Proposed devices in this submission are substantially equivalent to the predicate devices Therefore we didn't consider conducting additional test but biocompatibility test and retention test of O-Ring are conducted because material of O-Ring is changed

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 Hiossen prosthetic system is substantially equivalent to the predicate devices as described herein.