K100245

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

AUG 17 2010

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: January 8, 2010

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
- Telephone No. :	82-51-850-2574
- Contact :	Mr. JongHyuk Seo

2. Device :

Trade or (Proprietary) Name :	HS/HG Prosthetic System
Common or usual name :	Dental Device
Classification Name :	Abutment, implant, dental, endosseous 21CFR872.3630 Class II NHA

3. Predicate Device :
The HU/HS/HG Prosthetic System, Osstem Implant Co., Ltd, K081575
The Ziocera & Convertible System, Osstem Implant Co., Ltd, K081786

4. Description :
1) The HS/HG Prosthetic System is device made of titanium, titanium alloy, POM and PC intended for use as an aid in prosthetic restoration. It consists of Abutment, Protect Cap and Abutment Screw. Its surfaces are partially Tin coated and uncoated.

2) The HS/HG 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 HS/HG Prosthetic System is substantially equivalent in design, function and intended use to the HU/HS/HG Prosthetic System (K081575) and Ziocera & Convertible System (K081786) of Osstem Implant Co., Ltd.

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- Substantial Equivalence Matrix

	HS/HG Prosthetic System	HU/HS/HG Prosthetic System (K081575)	Ziocera & Convertible System (K081786)
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
510(k) Number	New	K081575	K081786
Intended use	HS/HG 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 with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Ziocera & Convertible System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Packaging	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack
Sterilization	Healing Abutment – Radiation Sterile Abutment – Non-Sterile	Healing Abutment – Radiation Sterile Abutment – Non-Sterile	Non-Sterile
Shelf life	5 years	5 years	-

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

6. Review :
The HS/HG Prosthetic System has similar material, indication for use, design and technological characteristics as the predicate device.

The HS/HG Prosthetic 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 nonclinical testing
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" with the worst case scenario. The fatigue test result were Similar to previously cleared predicate device.

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8. Conclusion :

Based on the information provided in this premarket notification Osstem concludes that the HS/HG Prosthetic System is substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Osstem Implant Company, Limited
C/O Mr. Patrick Lim
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

AUG 17 2010

Re: K100245
Trade/Device Name: HS/HG Prosthetic System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 11, 2010
Received: August 13, 2010

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, and General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 100245

Device Name : HS/HG Prosthetic System

Indication for use : HS/HG 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)

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

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