

K091208

510(k) Summary

MAR - 3 2010

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

Date: April 24, 2009

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. JongHyuk Seo

2. Device :

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

3. Predicate Device :

The HG III Fixture System, HIOSSEN Inc, K082213
The Ziocera & Convertible System, OSSTEM Implant Co., Ltd, K081786

4. Description :

The GS III System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.

The GS III 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 GS III System is substantially equivalent in design, function and intended use to the HGIII Fixture System(K082213) of HIOSSEN Inc and Ziocera & Convertible System(K081786) of OSSTEM Implant Co., Ltd.

The HG/GS 3.5 mm fixtures are not intended to be used with HG Ziocera angled abutment

5. Indication for use :

The GS III 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 GS III System is for single and two stage surgical procedures. It is not for immediate load.

6. Review :

The GS III System has same material and indication for use and similar design and technological characteristics as the predicate device.

The GS III 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. Conclusion :

Based on the information provided in this premarket notification Osstem concludes that the GS III System is safe and effective and 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 Implants, Company Limited
C/O Mr. Patrick Lim
Manager
Hiossen, Incorporated
85 Ben Fairless Hills
Fairless, Pennsylvania 19030

MAR - 3 2010

Re: K091208
Trade/Device Name: GSIII System
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 1, 2010
Received: March 2, 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.

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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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Number K 091208

Device Name: GSIII System

Indication for use : The GSIII 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 GSIII System is for single and two stage surgical procedures. It is not for immediate load.

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)

RS Betz DDS for Dr. K.P. Mulry
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

10(k) Number: K091208