K132067

OSSTEM® IMPLANT **OSSTEM Implant Co., Ltd.**
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
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DEC 2 0 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: June 27, 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 :	Multi Angled Abutment system
Common or usual name :	Dental Abutment
Classification Name :	Abutment, implant, dental, endosseous 21CFR872.3630 Class II NHA

3. Predicate Device :
Multi Angled Abutment, OSSTEM Implant Co., Ltd., K123755

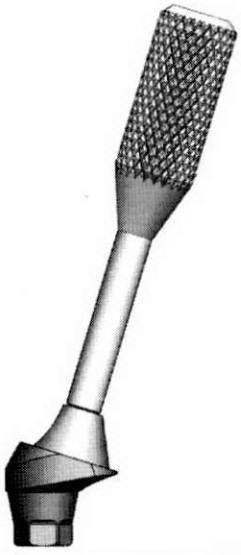
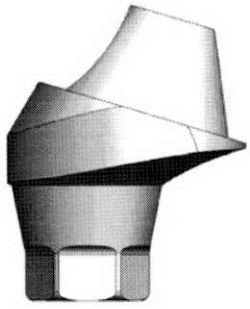
4. Description :

The Multi Angled Abutment is device made of titanium alloy intended for use as an aid in prosthetic restoration.
The Multi Angled Abutment is used with Esthetic -low Cylinders (only Non-Hex) in the US System, K62030 and connected to HTIII SA Fixture in the HTIII SA Fixture System, K101096

1) The Multi Angled Abutment system consists of Abutment combined carrier that is tool to carry Multi angled abutment. and Abutment Screw.

2) The Multi Angled Abutment system is exactly same with Multi Angled Abutment (K123755) except combined carrier

- Substantial Equivalence Matrix

	Multi Angled Abutment system	**Multi Angled Abutment**
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
510(k) Number	New	K123755
Design		
Intended use	Multi Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as bridges, or overdentures.	Multi Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as bridges, or overdentures.
Abutment Angle(°)	17, 30	17, 30
platform(Ø)	4.8	4.8
Connection	The Multi Angled Abutment system is exactly same with Multi Angled Abutment(K123755) except combined carrier. Carrier is just to carry the Multi Angled Abutment to implanted Fixture	

5. Indication for use :
The Multi Angled Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as bridges, or overdentures.

6. Review :

The Multi Angled Abutment system is merely improved for movement convenience of abutment by combination of carrier therefore, The Multi Angled Abutment is nothing changed from predicated Multi Angled Abutment (K123755) except combined carrier

7. Summary of nonclinical testing

The risks associated with the modification were evaluated via a DCAS table and it was determined that no performance testing is needed. However, minor modifications were made to the labeling.

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 Multi Angled Abutment 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

December 20, 2013

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

Re: K132067
Trade/Device Name: Multi Angled Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 31, 2013
Received: November 25, 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,

Kwame O. Ulmer -S 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 132067

Device Name : Multi Angled Abutment system

Indication for use : Multi Angled Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as 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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