

DEC 11 2012

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: May 30, 2012

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 |
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| - Correspondent's Name: | HIOSEN Inc. |
| - Address: | 85 Ben Fairless Dr. Fairless Hills, PA 19030 |
| - Contact: | Patrick Lim |
| - Phone: | 888 678 0001 |

2. Device :

- | | |
|-------------------------------|--|
| Trade or (Proprietary) Name : | NP-Cast Abutment System |
| Common or usual name : | Dental Device |
| Classification Name : | Endosseous dental implant abutment
21CFR872.3630
Class II
NHA |

3. Predicate Device :

- SimpleLine II Abutment System, Dentium Co., Ltd., K112045
 Prosthetic System, OSSTEM Implant Co., Ltd., K110308
 HU.HS.HG Prosthetic System, OSSTEM Implant Co., Ltd., K081575

4. Description :

NP-Cast Abutment System is used for prosthetic restoration. It is used for cases with path and aesthetic and spatial constraints. After customization, be sure to use only dental non-precious metal (Co-Cr-Mo alloy) for casting to make the prosthesis
 When cast a prosthesis with NP-Cast Abutment System, Post height above the transmucosal collar of NP-Cast Abutment System has to be taller than 4mm and
 Maximum angulation has to be less than 30°

- 1) The NP-Cast Abutment System consists of Abutment and Abutment Screws.
And Abutment in the NP-Cast Abutment System is distinguished such as below

Model Name	Product name	Connection		Diameter
NP-Cast Abutment System	NP Cast Abutment	Mini	Hex,	Ø4.0mm
			Non Hex	Ø 4.0mm
		Standard	Hex,	Ø 4.5mm
			Non Hex	Ø 4.5mm
	HS NP Cast Abutment	Mini	Octa,	Ø 5.05mm
			Non Octa	Ø 6.3mm
Standard		Octa,	Ø 5.05mm	
		Non Octa	Ø 6.3mm	

- 2) The NP-Cast Abutment 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 NP-Cast Abutment System is substantially equivalent in design, function and intended use to The SimpleLine II Abutment System(K112045) of Dentium Co., Ltd. and Prosthetic System (K110308) of OSSTEM Implant Co., Ltd., HU.HS.HG Prosthetic System (K081575) of OSSTEM Implant Co., Ltd.

- Substantial Equivalence Matrix

	NP-Cast Abutment	SimpleLine II Abutment System	Prosthetic System
Manufacturer	Osstem Implant Co., Ltd	Dentium Co., Ltd.	Osstem Implant Co., Ltd
510(k) Number	New	K112045	K110308
Intended use	NP-Cast Abutment 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.	Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Material	Co-Cr-Mo Alloy	Co-Cr-Mo Alloy	Gold Alloy

5. Indication for use :

The NP-Cast Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

6. Review :

The NP-Cast Abutment System has similar material, indication for use, design and technological characteristics as the predicate device.

7. Summary of nonclinical testing

Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable international and US regulations.

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 of the NP-Cast Abutment System

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 NP-Cast Abutment System is substantially equivalent to the predicate devices as - described herein.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

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

Re: K121843

Trade/Device Name: NP-Cast Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 28, 2012
Received: December 5, 2012

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
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 121843

Device Name : NP-Cast Abutment System

Indication for use : NP-Cast Abutment 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)

Susan Runner DDS, MA 2012.12.11
15:23:21 -05'00'

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

510(k) Number: K121843