K103105

OSSTEM IMPLANT **OSSTEM Implant Co., Ltd.**
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MAR 2 5 2011

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: Oct 6, 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 :	Orthodontic Screw System
Common or usual name :	Dental
Classification Name :	implant, endosseous, orthodontic 21CFR872.3640 Class II OAT

3. Predicate Device :
The Super Orthodontic Screw System, OSSTEM Implant Co., Ltd, K062156

4. Description :
The Orthodontic Screw is a dental implant system made of titanium metal intended to be used as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is 1.4, 1.6 and 1.8mm in screw diameter and 6, 8, 10mm in length. It is made of Titanium alloy (Ti-6Al-4V ELI, ASTM F 136- 02A). The surface of the screw is non-treated.

- Substantial Equivalence Matrix

	Orthodontic screw	Predicate devices Super Orthodontic screw (K062156)
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
Indication For Use	The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only	The Super Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only
Structure	Through Hole : Wire hole Simple Head : No hole Tapered body	Slot Wire hole Tapered body
Diameter (D) **Length (mm)**	Refer to the Table 1	
Material of Fixture	Titanium alloy (Ti-6Al-4V ELI) (ASTM F 136- 02A)	Titanium alloy (Ti-6Al-4V ELI) (ASTM F 136- 02A)
Sterilization	Radiation Sterile	Radiation Sterile
Shelf life	5 years	5 years
S & E	The Orthodontic screw system has same material and indication for use and similar design and technological characteristics as the predicate device.	

Orthodontic screw		Predicate devices Super Orthodontic screw (K062156)	
(Ø)	(mm)	(Ø)	(mm)
1.4	6.0, 8.0	-	-
1.6	6.0, 8.0, 10.0	1.6	6.0, 8.0, 10.0
1.8	6.0, 8.0, 10.0	1.8	6.0, 8.0, 10.0

Table 1. Diameter and length (Orthodontic screw and Predicate devices)

5. Indication for use :
The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only

6. Review :
The Orthodontic screw system has same material and indication for use and similar design and technological characteristics as the predicate device.

The Orthodontic screw 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
Fracture load test was done in accordance with Osstem standard (Fracture & Bending test, OS-C-0013) and result is in compliance with it.
Rotational Fracture torque test was done in accordance with Osstem standard (Rotational Fracture torque test, OS-C-0012) and result is in compliance with it.

8. Summary of clinical testing
No clinical studies are submitted

9. Conclusion :
Based on the information provided in this premarket notification Osstem concludes that the Orthodontic screw 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 Implant, Limited
C/O Mr. Patrick Lim
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

MAR 25 2011

Re: K103105
Trade/Device Name: Orthodontic Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 23, 2011
Received: February 24, 2011

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,

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 103105

Device Name: Orthodontic Screw

Indication for use : The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only

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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