



Food and Drug Administration  
10903 New Hampshire Avenue  
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December 21, 2016

Osstem Implant Co., Ltd.  
% David Kim  
Manager  
Hiossen Inc.  
85 Ben Fairless Dr.  
Fairless Hills, Pennsylvania 19030

Re: K161197  
Trade/Device Name: Orthodontic Screw  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: OAT  
Dated: November 23, 2016  
Received: November 23, 2016

Dear David Kim:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

  
**Michael J. Ryan -S**

for Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



# OSSTEM Implant Co., Ltd.

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Section 12

## Indications for Use Statement

### Indications for Use

510(k) Number : K161197

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## 510(k) Summary

Date: December 13, 2016

### 1. Company and Correspondent making the submission:

- |                         |   |
|-------------------------|---|
| - Submitter's Name :    | OSSTEM Implant Co., Ltd.  |
| - Address :             | 66-16, Bansong-ro 513beon-gil, Haeundae-gu,<br>Busan, Republic of Korea |
| - Contact :             | Mr. Hee Kwon Son  |
| - Phone:                | +82 51 850 2575   |
| - Correspondent's Name: | HIOSSSEN Inc.   |
| - Address:              | 85 Ben Fairless Dr. Fairless Hills, PA 19030                            |
| - Contact:              | DAVID KIM   |
| - Phone:                | 267 759 7031  |

### 2. Device :

- |                               |                                  |
|-------------------------------|----------------------------------|
| Trade or (Proprietary) Name : | Orthodontic Screw                |
| Device Name :                 | Implant, Endosseous, Orthodontic |
| Regulation Name :             | Endosseous Dental Implant        |
| Regulation Number :           | 21 CFR 872.3640                  |
| Device Classification:        | Class II                         |
| Product Code:                 | OAT                              |

### 3. Predicate Device :

Primary Predicate

K103105, Orthodontic screw, Osstem implant co.,Ltd

Reference predicate

K122171, MS SA Implant System, Osstem implant co.,Ltd

K060126, Absoanchor Microimplant, Dentos Inc

### 4. Device Description :

This product is orthodontic screw used for straightening of irregular teeth.

It is designed for indications such as malocclusion treatment, straightening of irregular teeth, improvement of intermaxillary space and occlusion, and maintenance after orthodontic treatment.

It is surgically placed in the bone of the upper or lower jaw arches to provide support for orthodontic devices and it is used temporarily and is removed after orthodontic treatment has been completed.

Orthodontic screw is designed to facilitate placement of orthodontic appliances such as wires, springs, and elastic ligatures.

The Orthodontic Screw is a dental device made of titanium alloy metal intended to be used as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

It is 1.2, 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).




There are two types of surface treatment one is non-treated (Machined) another one is Acid etching

Product Name	Content	
Orthodontic Screw (Simple Head)	Head Features	Low head height(1.95mm) and smooth curved head
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.2, 1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Machined (Not acid etched)
Orthodontic Screw (Through Hole)	Head Features	Head height(2.15mm) and smooth curved head Wire Can be used up to 022" wire using by hole Hole diameter : Ø0.8
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.2, 1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Machined (Not acid etched)
Orthodontic Screw (Small Head)	Head Features	Min. Head Size(1.48mm) and Head height(1.95mm) smooth curved head
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Machined (Not acid etched)
Orthodontic Screw (Bracket Head)	Head Features	Wire compatibility through cross-shaped slot
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Machined (Not acid etched)
Orthodontic Screw (Half Etched-Simple Head)	Head Features	Low head height(1.95mm) and smooth curved head
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.2, 1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Acid etching

Orthodontic Screw (Half Etched-Through Hole)	Head Features	Head height(2.15mm) and smooth curved head Wire Can be used up to 022" wire using by hole Hole diameter : Ø0.8
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.2, 1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Acid etching
Orthodontic Screw (Half Etched-Small Head)	Head Features	Min. Head Size(1.48mm) and Head height(1.95mm) smooth curved head
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Acid etching
Orthodontic Screw (Half Etched-Bracket Head)	Head Features	Wire compatibility through cross-shaped slot
	Material	Titanium alloy, Ti-6Al-4V ELI
	Diameter (mm)	Ø1.4, 1.6, 1.8
	Length (mm)	6, 8, 10
	Surface	Acid etching




**- Substantial Equivalence Matrix**

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

	Orthodontic screw	Primary Predicate	Reference predicate
		Orthodontic screw	Absoanchor Microimplant
<b>510(K) No.</b>	K161197	K103105	K060126
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	Dentos Inc
<b>Design</b>			
<b>Intended use</b>	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	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	Provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

	completed. Screws are intended for single use only	removed after orthodontic treatment has been completed. Screws are intended for single use only	
<b>Head structure</b>	Simple Head, Through Hole, Small Head, Bracket Head	Simple Head, Through Hole	1.Small head 2.No head 3.Long head 4.Circle head 5.Fixation head 6.Bracket head 7.Bracket head-left handed screw 8.OMAS mushroom
<b>Body Diameter (D)</b>	Ø1.2mm, Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	Ø 1.2mm - Ø 1.8mm
<b>Length (mm)</b>	6mm, 8mm, 10mm	6mm, 8mm, 10mm	4mm -10mm & 12mm
<b>Material of Fixture</b>	Ti-6Al-4V ELI, ASTM F 136	Ti-6Al-4V ELI, ASTM F 136	Ti-6Al-4V ELI, ASTM F 136
<b>Surface</b>	Machined	Machined	-
<b>Sterilization</b>	Radiation Sterile	Radiation Sterile	Non-Sterile ; Steam Sterilize before use
<b>Shelf life</b>	8 years	5 years	-
<b>Target population</b>	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.
<b>principles of operation</b>	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	
<b>S E</b>	<p>Orthodontic screw has been predicated by 510(K), K103105 but It is resubmitted to add Ø1.2mm Diameter and Small Head, Bracket Head type orthodontic screw</p> <p>We conducted performance test due to addition of smaller diameter Ø1.2mm Fracture load Test, Rotational fracture torque test, Axial pull-out strength test</p> <p>We state Orthodontic screw is not different from predicate, the Orthodontic screw (K103105) and Absoanchor Microimplant (K060126) on the safety and effectiveness.</p>		

	Because Orthodontic screw has the same principles of operation, material, indication for use and similar design (Diameter and length are also included in dimension range of predicate) as the predicate
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	Orthodontic screw	Primary Predicate	Reference predicate
		Orthodontic screw	MS SA Implant System
<b>510(K) No.</b>	K161197	K103105	K122171
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Design</b>			
<b>Intended use</b>	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 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 MS SA Implant (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MS SA Implant (Narrow Ridge) is intended for single use only. It is intended for delayed loading.
<b>Head structure</b>	Simple Head, Through Hole, Small Head, Bracket Head	Simple Head, Through Hole	-
<b>Body Diameter (D)</b>	Ø1.2mm, Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	Ø2.5mm, Ø 2.9mm
<b>Length (mm)</b>	6mm, 8mm, 10mm	6mm, 8mm, 10mm	8.5, 10.0, 11.5, 13.0mm
<b>Material of Fixture</b>	Titanium alloy Ti-6Al-4V ELI, ASTM F 136	Titanium alloy Ti-6Al-4V ELI, ASTM F 136	Titanium alloy Ti-6Al-4V ELI, ASTM F 136
<b>Surface</b>	Acid etching	Machined	SA(Sandblasting and Acid etching).
<b>Sterilization</b>	Radiation Sterile	Radiation Sterile	Radiation Sterile
<b>Shelf life</b>	8 years	5 years	8 years
<b>Target</b>	Professional use only –	Professional use only –	Professional use only –



<b>population</b>	qualified dentists. Strictly reserved to specialized and trained users.	qualified dentists. Strictly reserved to specialized and trained users.	qualified dentists. Strictly reserved to specialized and trained users.
<b>principles of operation</b>	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	
<b>S E</b>	<p>Orthodontic screw has been predicated by 510(K), K103105 but It is resubmitted to add Ø1.2mm Diameter, and Small Head, Bracket Head type orthodontic screw and change surface that is Acid etching</p> <p>We conducted performance test due to addition of smaller diameter Ø1.2mm. Surface treatment of Orthodontic screw is same with MS SA Implant System except Sand Blasting process of MS SA Fixture, Therefore we certify that Orthodontic Screw is same with MS SA Fixture from a Biocompatibility point of view</p> <p>We state Orthodontic screw is not different from predicate, the Orthodontic screw (K103105) and Absoanchor Microimplant (K060126) on the safety and effectiveness.</p> <p>Because Orthodontic screw has the same principles of operation, material, indication for use and similar design (Diameter and length are also included in dimension range of predicate) as the predicate</p>		

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. Summary of nonclinical testing

The Orthodontic screw system has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been considered to ensure the devices comply with the applicable International and US regulations.

Performance Testing of Orthodontic screw is conducted

- Fracture load Test
- Rotational fracture torque test
- Axial pull-out strength test

Biocompatibility for the Orthodontic screw is demonstrated by the reference to K122171. Validation of the gamma irradiation process is demonstrated by the reference to K072896. Surface treatment characterization testing is demonstrated by the reference to K122171.



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K161197

## 7. Summary of clinical testing

No clinical studies are submitted

## 8. 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 Orthodontic screw is substantially equivalent to the predicate devices as described herein.