



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 25, 2017

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

Re: K160670  
Trade/Device Name: ET US SS Prosthetic System  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: Class II  
Product Code: NHA  
Dated: April 12, 2017  
Received: April 12, 2017

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,

**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.

66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea  
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

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## Indications for Use Statement

510(k) Number   K160670  

Device Name: ET US SS Prosthetic system

Indication for use:

### **ET System**

The HIOSSEN Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

### **US/SS System**

The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

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)



# OSSTEM Implant Co., Ltd.

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Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

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## 510(k) Summary

Date: April 25, 2017

### 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: | ET US SS Prosthetic system         |
| Common or Usual Name:        | Dental Abutment                    |
| Classification Name:         | Endosseous dental implant abutment |
| Regulation Number:           | 21CFR872.3630                      |
| Device Classification:       | Class II                           |
| Product Code:                | NHA                                |

### 3. Predicate Device:

#### Primary Predicate

K062030 US System, OSSTEM IMPLANT CO.,LTD

#### Reference Predicates

K121585 TS Implant System, OSSTEM IMPLANT CO.,LTD

K100245 HS, HG Prosthetic System, OSSTEM IMPLANT CO.,LTD

K130662 ET Prosthetic System, OSSTEM IMPLANT CO.,LTD

K062051 SS System, OSSTEM IMPLANT CO.,LTD

K073247 US.SS.GS System, OSSTEM IMPLANT CO.,LTD K121843

NP Cast Abutment System, OSSTEM IMPLANT CO.,LTD K081575

HU.HS.HG Prosthetic System, OSSTEM IMPLANT CO.,LTD

K132067 Multi Angled Abutment with carrier, OSSTEM IMPLANT CO.,LTD

#### 4. Description:

The ET US SS Prosthetic system is intended for use as an aid in prosthetic restoration. It is consisted of abutments, components and abutment screws.

The ET US SS Prosthetic 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 ET US SS Prosthetic system is substantially equivalent in design, function and intended use to the Predicate Devices as above.

#### ET System

Item	Content	
Quick Temporary Abutment	Description	Used temporary until final prosthesis is made to maintain esthetic appearance. Quick Temporary Abutment Set is consisted of Quick Temporary Abutment and Ti Screw.
	Material	Titanium Alloy + Plastic (Polyetheretherketone)
	Diameter (mm)	4, 4.5
	Height (mm)	13.9, 14.3, 14.5, 14.6, 17.4, 17.8, 18.0, 18.1
Multi Abutment	Description	Used for edentulous mandible or maxilla. Usually use to make full denture. Screw Retained Restoration. Used in screw type prosthetics in multiple cases. Multi Abutment Set is consisted of Multi Abutment and Multi Abutment Carrier.
	Material	Titanium Alloy (TiN Coating)
	Diameter (mm)	4.8
	Height (mm)	8.3, 8.7, 9.3 9.7, 10.3, 10.7, 11.3, 11.7, 12.3, 12.7

#### SS System

Item	Content	
Solid Abutment	Description	Used in producing ordinary cement-retained prosthetics. Solid Abutment Set is consisted of Solid Abutment and Solid Protect Cap.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	3.5, 4.3
	Height (mm)	9.5, 9.8, 11, 11.3, 12.5, 12.8
Solid Protect Cap	Description	Used to protect Solid abutments in the oral cavity.
	Material	Polymer (Polycarbonate)
	Diameter (mm)	5.3, 6.02
Excellent Solid Abutment	Description	Used in producing cement-retained prosthetics. Excellent Solid Abutment Set is consisted of Excellent Solid Abutment and Solid Protect Cap.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	4.3, 5.29

	Height (mm)	9.5, 9.7, 11, 11.2, 12.5, 12.7
Excellent Solid Protect Cap	Description	Used to protect Excellent Solid Abutments in the oral cavity.
	Material	Polymer (Polycarbonate)
	Diameter (mm)	5.3, 6.6
ComOcta Abutment	Description	Used for making general cement-type prosthesis. ComOcta Abutment is consisted of ComOcta Abutment and Ti Screw.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	4.3, 5.26
	Height (mm)	6.53, 6.55, 6.88, 6.90, 8.03, 8.05, 8.38, 8.40, 9.53, 9.55, 9.88, 9.90
ComOcta Plus Abutment	Description	Used for making general cement-type prosthesis and used when there is deep gingiva or a fixture is to be deeply inserted. Gold coloring on gingiva region is for aesthetics. ComOcta Plus Abutment Set is consisted of ComOcta Plus Abutment and Ti Screw.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	4.8, 6.0
	Height (mm)	6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10
ComOcta Angled Abutment	Description	Used for prosthetic restoration and path adjustment of prosthesis in case of 15° and 20° axial angle. ComOcta Angled Abutment Set is consisted of ComOcta Angled Abutment and Ti Screw.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	3.75, 4.3
	Height (mm)	5.5, 6.7
ComOcta Retraction Cap	Description	Used to protect ComOcta abutments in the oral cavity
	Material	Polymer (PolyOxy Methylene)
	Diameter (mm)	6.4, 7.7

## US System

Item	Content	
Cover Screw	Description	Used to protect other substances from ingressing into the fixture after the surgical operation.
	Material	Titanium (ASTM F 67)
	Diameter (mm)	3.7, 4.3, 5.2, 5.3
	Height (mm)	5.9
Healing Abutment	Description	Used to form the appropriate gingival shape after the second surgery.
	Material	Titanium (ASTM F 67)
	Diameter (mm)	4, 5, 6, 7
	Height (mm)	7.9, 8.9, 9.9, 11.4, 12.9
Cemented Abutment	Description	Used for making general cement-type prosthesis.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	4.0, 4.1, 5.0, 5.1, 6.0, 7.0

	Height (mm)	5.0, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0, 11.0
Ti Screw	Description	Used to connect abutment with fixture.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	2.3, 2.9, 3.2
	Height (mm)	8.0, 8.2
US Multi Angled Abutment	Description	If a few number of fixture were implanted in mandibular bone for making full denture, some of fixture path should be leaned. In that case, US Multi Angled Abutment is used to adjust path of prosthesis in case of 17 and 30° axial angle. US Multi Angled Abutment Set is consisted of US Multi Angled Abutment, Ti Screw, and Abutment Carrier.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	3.4, 4.0, 4.1
	Height (mm)	3.97, 3.98, 4.28, 4.77, 4.78, 5.28, 5.47, 6.28
Ti Screw	Description	Used to connect abutment with fixture.
	Material	Titanium Alloy (ASTM F 136)
	Diameter (mm)	2.2, 2.3
	Height (mm)	4.9, 5.55
Esthetic-low Abutment	Description	Used in producing screw-retained aesthetic prosthetics. Structure producing prosthetics in cylinder after attaching abutment in the oral cavity. Esthetic-low Abutment Set is consisted of Esthetic-low Abutment and Esthetic-low Abutment Screw.
	Material	Titanium (ASTM F67)
	Diameter (mm)	4.8, 5.5
	Height (mm)	2.1, 2.2, 3.0, 3.1, 4.0, 4.1, 5.0, 5.1
Esthetic-low Abutment Screw	Description	Used to connect Esthetic-low abutment with fixture.
	Material	Titanium (ASTM F67)
	Diameter (mm)	3.1, 3.6
	Height (mm)	7.8, 7.9, 8.8, 8.9, 9.8, 9.9, 10.8, 10.9
Esthetic-low Temporary Cylinder	Description	Used in producing temporary prosthetics. Esthetic-low Temporary Cylinder is consisted of Esthetic-low Temporary Cylinder and Ti Screw.
	Material	Titanium (ASTM F 67)
	Diameter (mm)	4.8, 5.5
	Height (mm)	12.0
O-ring Abutment	Description	Used in creating stud type overdenture prosthetics.
	Material	Titanium Alloy
	Diameter (mm)	5.0, 5.6
	Height (mm)	2.0, 3.0, 4.0, 5.0, 6.0

## 5. Indications for Use:

### ET System

The HIOSSEN Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

### US/ SS System

The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

## 6. Substantial Equivalence Matrix:



	Proposed Device	Primary Predicate Device	Reference Predicate
<b>510K</b>	-	K062030	K130662
<b>Indications for Use</b>	<p><b>ET System</b>            The HIOSSEN Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.</p> <p><b>US/ SS System</b>            The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.</p>	<p>Us system and ssii mini are intended 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. Us system is for two stage surgical procedures. It is not for one stage or immediate load. Ssii mini is for one and two stage surgical procedures. It is not for immediate load.</p>	<p>ET Prosthetic Systems is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</p>

The Indications for Use of the submission device differs from the primary predicate as in that the submission Indications are specific to the sub-set of devices, that is abutments, which have been included in the current submission. The primary predicate contains devices for a complete implant system and the Indications reflects this. Since the current submission is a sub-set of devices included in the primary predicate, the modification of the Indications to a sub-set of the primary predicate Indications is also appropriate. The Indications for the submission device are also identical to a reference predicate which only contains a similar abutment sub-set of devices.



Substantial Equivalence Matrixes for each specific device are provided as shown below.



Part Name	Proposed Device	Predicate Device
	Quick Temporary Abutment	Quick Temporary Abutment
<b>510K</b>	-	K121843
<b>Material</b>	Titanium Alloy PEEK	Titanium Alloy PEEK
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to make temporary prosthesis	Used to make temporary prosthesis
<b>Principles of Operation</b>	Quick Temporary Abutment is used in producing temporary	Quick Temporary Abutment is used in producing temporary





	prosthetics for immediate loading Upper part is made with plastic (PEEK) for easy altering/removing when make temporary prosthetics	prosthetics for immediate loading Upper part is made with plastic (PEEK) for easy altering/removing when make temporary prosthetics
<b>Dimension (Diameter)</b>	4mm, 4.5mm	4.5mm, 5.5mm
<b>Connection</b>	Internal Hex Connection	Internal Hex Connection
<b>Characteristic</b>	Cement retained restoration. Capable of easily altering/removing shape of plastic material. Abutment + Screw	Cement retained restoration. Capable of easily altering/removing shape of plastic material. Abutment + Screw
<b>Design</b>		
<b>S E</b>	<p>Difference:            Shape of upper part (Plastic part) is different from predicate, Quick Temporary Abutment            It is designed to be used when limitations in space (narrow space )</p> <p>The Quick Temporary Abutment had been cleared with K121585 but it is being submitted to add revised shape therefore Quick Temporary Abutment and Predicate devices have same principles of operation, function, material, Connection structure, characteristic and intended use</p>	



Part Name	Proposed Device	Predicate Device
	Solid Abutment	Solid Abutment
<b>510K</b>	-	K062051
<b>Material</b>	Titanium Alloy	Titanium Alloy
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to make Cement-retained prosthesis	Used to make Cement-retained prosthesis
<b>Principles of operation</b>	As general one body cement retained restoration, it is connected with fixture and cemented crown on the abutment	As general one body cement retained restoration, it is connected with fixture and cemented crown on the abutment
<b>Dimension (Height)</b>	9.5mm, 9.8mm, 11mm, 11.3mm, 12.5mm, 12.8mm	9.5mm, 9.8mm, 11mm, 11.3mm, 12.5mm
<b>Connection</b>	Internal Octa Connection	Internal Octa Connection
<b>Characteristic</b>	Cement retained restoration Abutment + Protect Cap	Cement retained restoration Abutment + Protect Cap



<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension is added.</p> <p>The Solid Abutment had been cleared with K062051, but it is being submitted to add a new dimension. Therefore, Solid Abutment and Predicate devices have same principles of operation, function, material, connection structure, characteristic and intended use.</p>	

Part Name	Proposed Device	Predicate Device
	Solid Protect Cap	Solid Protect Cap
<b>510K</b>	-	K062051
<b>Material</b>	Polymer (Polycarbonate)	Polymer (Polycarbonate)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to protect Solid Abutment in the oral cavity	Used to protect Solid Abutment in the oral cavity
<b>Principles of operation</b>	Solid Protect Cap is connected with Solid Abutment to protect in the oral cavity and minimize foreign body sensation by the patient	Solid Protect Cap is connected with Solid Abutment to protect in the oral cavity and minimize foreign body sensation by the patient
<b>Dimension (diameter)</b>	5.3mm, 6.02mm	5.5mm, 6.7mm
<b>Characteristic</b>	Protect abutment in the oral cavity	Protect abutment in the oral cavity
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension is added and shape is changed.</p> <p>The Solid Protect Cap had been cleared with K062051, but it is being submitted to add a new dimension added and its shape changed. Therefore, Solid Protect Cap and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	


Part Name	Proposed Device	Predicate Device
	Excellent Solid Abutment	Excellent Solid Abutment
<b>510K</b>	-	K062051
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to make Cement-retained prosthesis	Used to make Cement-retained prosthesis
<b>Principles of operation</b>	As general one body cement retained restoration, it is connected with fixture and cemented crown on the abutment	As general one body cement retained restoration, it is connected with fixture and cemented crown on the abutment
<b>Dimension (Height)</b>	9.5mm, 9.7mm, 11mm, 11.2mm, 12.5mm, 12.7mm	9.5mm, 9.7mm, 11mm, 11.2mm, 12.5mm
<b>Connection</b>	Internal Octa Connection	Internal Octa Connection
<b>Characteristic</b>	Cement retained restoration Abutment + Protect Cap	Cement retained restoration Abutment + Protect Cap
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension is added.</p> <p>The Excellent Solid Abutment had been cleared with K062051, but it is being submitted to add a new dimension. Therefore, Solid Abutment and Predicate devices have same principles of operation, function, material, connection structure, characteristic and intended use.</p>	

Part Name	Proposed Device	Predicate Device
	Excellent Solid Protect Cap	Excellent Solid Protect Cap
<b>510K</b>	-	K062051
<b>Material</b>	Polymer (Polycarbonate)	Polymer (Polycarbonate)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to protect Excellent Solid Abutment in the oral cavity	Used to protect Excellent Solid Abutment in the oral cavity
<b>Principles of operation</b>	Excellent Solid Protect Cap is connected with Solid Abutment to protect in the oral cavity and minimize foreign body sensation by the patient	Excellent Solid Protect Cap is connected with Solid Abutment to protect in the oral cavity and minimize foreign body sensation by the patient
<b>Dimension (Height)</b>	6.35mm, 7.85mm, 9.35mm, 9.65mm	6.35mm, 7.85mm, 9.35mm

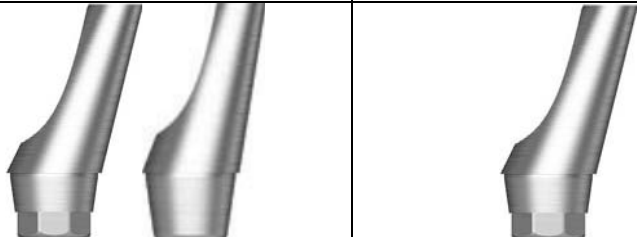
<b>Characteristic</b>	Protect abutment in the oral cavity	Protect abutment in the oral cavity
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension is added.</p> <p>The Excellent Solid Protect Cap had been cleared with K062051, but it is being submitted to add a new dimension. Therefore, Solid Protect Cap and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	

<b>Part Name</b>	<b>Proposed Device</b>	<b>Predicate Device</b>
	ComOcta Abutment	ComOcta Abutment
<b>510K</b>	-	K073247
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to make Cement-retained prosthesis	Used to make Cement-retained prosthesis
<b>Principles of operation</b>	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment
<b>Dimension (Height)</b>	6.53mm, 6.55mm, 6.88mm, 6.90mm, 8.03mm, 8.05mm, 8.38mm, 8.40mm, 9.53mm, 9.55mm, 9.88mm, 9.90mm	6.53mm, 6.55mm, 6.88mm, 6.90mm, 8.03mm, 8.05mm, 8.38mm, 8.40mm, 9.53mm, 9.55mm
<b>Connection</b>	Internal Octa Connection	Internal Octa Connection
<b>Characteristic</b>	Cement retained restoration Abutment + Screw	Cement retained restoration Abutment + Screw
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimensions are added.</p> <p>The ComOcta Abutment had been cleared with K062051, but it is being submitted to add new dimension. Therefore, ComOcta Abutment and</p>	



	Predicate devices have same principles of operation, function, material, connection structure, characteristic and intended use.
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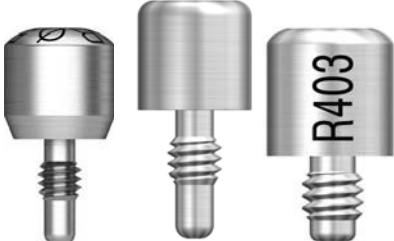

Part Name	Proposed Device	Predicate Device
	ComOcta Plus Abutment	ComOcta Plus Abutment
<b>510K</b>	-	K073247
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to make Cement-retained prosthesis Used when there is deep gingiva or a fixture is to be deeply inserted	Used to make Cement-retained prosthesis Used when there is deep gingiva or a fixture is to be deeply inserted
<b>Principles of operation</b>	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment
<b>Dimension (Height)</b>	6.5mm, 7mm, 7.5mm, 8mm, 8.5mm, 9mm, 9.5mm, 10mm	7.5mm, 8mm, 9.5mm, 10mm
<b>Connection</b>	Internal Octa Connection	Internal Octa Connection
<b>Characteristic</b>	Cement retained restoration Abutment + Screw Gold coloring on gingiva region for aesthetics	Cement retained restoration Abutment + Screw Gold coloring on gingiva region for aesthetics
<b>Design</b>		
<b>S E</b>	Difference: New dimensions and Non-Octa type abutments are added.  The ComOcta Plus Abutment had been cleared with K073247, but it is being submitted to add new dimensions and Non-Octa type abutments. Therefore, ComOcta Plus Abutment and Predicate devices have same principles of operation, function, material, characteristic and intended use.	

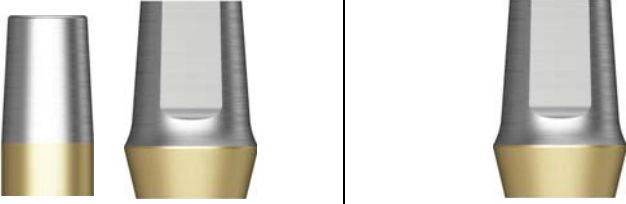
Part Name	Proposed Device	Predicate Device
	ComOcta Angled Abutment	ComOcta Angled Abutment
<b>510K</b>	-	K073247
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description</b>	Used for prosthetic restoration	Used for prosthetic restoration

<b>(Intended for use)</b>	Used for the path adjustment of prosthesis in case of 15° and 20° axial angle	Used for the path adjustment of prosthesis in case of 15° and 20° axial angle
<b>Principles of operation</b>	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment ComOcta Angled Abutment has 15° and 20° axial angle for path adjustment of prosthesis	As general type cement retained restoration, it is connected with fixture and cemented crown on the abutment ComOcta Angled Abutment has 15° and 20° axial angle for path adjustment of prosthesis
<b>Dimension (diameter)</b>	3.75mm, 4.3mm	3.75mm, 4.3mm
<b>Connection</b>	Internal Octa Connection	Internal Octa Connection
<b>Characteristic</b>	Cement retained restoration Abutment + Screw	Cement retained restoration Abutment + Screw
<b>Design</b>		
<b>S E</b>	<p>Difference: Non-Octa type abutments are added.</p> <p>The ComOcta Angled Abutment had been cleared with K073247, but it is being submitted to add Non-Octa type. Therefore, ComOcta Angled Abutment and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	

Part Name	Proposed Device	Predicate Device
	Cover Screw	Cover Screw
<b>510K</b>	-	K062030
<b>Material</b>	Titanium (ASTM F 67)	Titanium (ASTM F 67)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to protect other substances from ingressing into the fixture after the surgical operation	Used to protect other substances from ingressing into the fixture after the surgical operation
<b>Principles of operation</b>	Cover Screw is connected with implanted fixture to protect other substances from ingressing into the fixture after the surgical operation	Cover Screw is connected with implanted fixture to protect other substances from ingressing into the fixture after the surgical operation
<b>Dimension (diameter)</b>	3.7mm, 4.3mm, 5.2mm, 5.3mm	3.7mm, 4.3mm, 5.3mm
<b>Characteristic</b>	Used to protect other substances from ingressing into the fixture	Used to protect other substances from ingressing into the fixture



<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension is added.</p> <p>The Cover Screw had been cleared with K062030, but it is being submitted to add a new dimension. Therefore, Cover Screw and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	

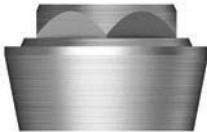
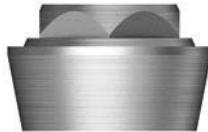
Part Name	Proposed Device	Predicate Device
	Healing Abutment	Healing Abutment
<b>510K</b>	-	K062030
<b>Material</b>	Titanium (ASTM F 67)	Titanium (ASTM F 67)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to form the appropriate gingival shape after the second surgery	Used to form the appropriate gingival shape after the second surgery
<b>Principles of operation</b>	Healing Abutment is connected with implanted fixture to form the appropriate gingival shape after the second surgery	Healing Abutment is connected with implanted fixture to form the appropriate gingival shape after the second surgery
<b>Dimension (diameter)</b>	4mm, 4.13mm, 5mm, 5.1mm, 5.13mm, 6mm, 7mm	4mm, 5mm, 6mm, 7mm
<b>Characteristic</b>	Used to protect other substances from ingressing into the fixture	Used to protect other substances from ingressing into the fixture
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimensions and shape are added.</p> <p>The Healing Abutment had been cleared with K062030, but it is being submitted to add new dimensions and shape. Therefore, Healing Abutment and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	

Part Name	Proposed Device	Predicate Device
	Cemented Abutment	Cemented Abutment
<b>510K</b>	-	K073247
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to make Cement-retained prosthesis	Used to make Cement-retained prosthesis
<b>Principles of operation</b>	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment
<b>Dimension (diameter)</b>	4.0mm, 4.1mm, 5.0mm, 5.1mm, 6.0mm, 7.0mm	4.0mm, 5.0mm, 6.0mm, 7.0mm
<b>Connection</b>	External Hex Connection	External Hex Connection
<b>Characteristic</b>	Cement retained restoration Abutment + Screw	Cement retained restoration Abutment + Screw
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension are added.</p> <p>The Cemented Abutment had been cleared with K073247, but it is being submitted to add a new dimension. Therefore, Cemented Abutment and Predicate devices have same principles of operation, function, material, connection structure, characteristic and intended use.</p>	



Part Name	Proposed Device	Predicate Device
	Ti Screw	Ti Screw
<b>510K</b>	-	K062030
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to connect abutment with fixture	Used to connect abutment with fixture
<b>Principles of operation</b>	Connect an abutment with fixture using by screw	Connect an abutment with fixture using by screw
<b>Dimension (diameter)</b>	2.3mm, 2.9mm, 3.2mm	2.5mm, 2.6mm, 2.9mm, 3.2mm
<b>Characteristic</b>	Connect an abutment with fixture	Connect an abutment with fixture





<b>Design</b>		
<b>S E</b>	<p>Difference: New dimension is added.</p> <p>The Ti Screw had been cleared with K062030, but it is being submitted to add new code for new dimension added. Therefore, Ti Screw and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	

Part Name	Proposed Device	Predicate Device
	Esthetic-low Abutment	Esthetic-low Abutment
<b>510K</b>	-	K062030
<b>Material</b>	Titanium (ASTM F67)	Titanium (ASTM F67)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used in producing screw-retained aesthetic prosthetics Structure producing prosthetics in cylinder after attaching abutment in the oral cavity	Used in producing screw-retained aesthetic prosthetics Structure producing prosthetics in cylinder after attaching abutment in the oral cavity
<b>principles of operation</b>	Esthetic-low abutment is connected to implanted fixture and upper part is connected to cylinder Esthetic-low abutment uses cylinder screw to fasten screw-retained type prosthesis	Esthetic-low abutment is connected to implanted fixture and upper part is connected to cylinder Esthetic-low abutment uses cylinder screw to fasten screw-retained type prosthesis
<b>Dimension (Diameter of Connection)</b>	2.41mm, 2.71mm, 3.41mm	2.71mm, 3.41mm
<b>Connection</b>	External Hex Connection	External Hex Connection
<b>Characteristic</b>	Screw retained prosthesis	Screw retained prosthesis
<b>Design</b>		
<b>S E</b>	<p>Difference: New dimensions are added.</p> <p>The Esthetic-low Abutment had been cleared with K062030, but it is being submitted to add new dimensions. Therefore, Esthetic-low Abutment and Predicate devices have same principles of operation,</p>	



	function, material, connection structure, characteristic and intended use.
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Part Name	Proposed Device	Predicate Device
	O-ring Abutment	O-ring Abutment
<b>510K</b>	-	K062030
<b>Material</b>	Titanium Alloy	Titanium Alloy
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used in creating stud type overdenture prosthetics	Used in creating stud type overdenture prosthetics
<b>principles of operation</b>	O-ring abutment is generally applied to prosthetic procedure for overdentures. Its O-ring attachment retained abutment, connected to fixture, and then acts as the male counterpart	O-ring abutment is generally applied to prosthetic procedure for overdentures. Its O-ring attachment retained abutment, connected to fixture, and then acts as the male counterpart
<b>Dimension (diameter)</b>	5.0mm, 5.6mm	5.0mm
<b>Connection</b>	External Hex Connection	External Hex Connection
<b>Characteristic</b>	Stud type overdenture prosthesis	Stud type overdenture prosthesis
<b>Design</b>		
<b>S E</b>	Difference: New dimensions are added.  The O-ring Abutment had been cleared with K062030, but it is being submitted to add new dimensions added. Therefore, O-ring Abutment and Predicate devices have same principles of operation, function, material, connection structure, characteristic and intended use.	



Part Name	Proposed Device	Predicate Device
	ComOcta Retraction Cap	Excellent Solid Retraction cap
<b>510K</b>	-	K100245
<b>Material</b>	Polymer (POM)	Polymer (POM)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.



<b>Description (Intended for use)</b>	Used to protect ComOcta abutments in the oral cavity and minimize foreign body sensation by the patient Accurate margin impression function when taking impression directly from a ComOcta abutment	Used for the protection of the Excellent solid abutment on the oral cavity and to minimize the patient's discomfort.
<b>Dimension (Diameter)</b>	6.4, 7.7mm	6.4, 7.7mm
<b>Design</b>		
<b>Principles of operation</b>	ComOcta Retraction Cap is temporary connected with ComOcta abutment for minimize foreign body sensation by the patient and accurate margin impression function when taking impression directly from a ComOcta abutment	Excellent Solid Retraction Cap is temporary connected with Excellent Solid abutment for minimize foreign body sensation by the patient and accurate margin impression function when taking impression directly from a Excellent solid abutment
<b>S E</b>	Different Only connection shape is different because of difference of compatible abutment post shape  ComOcta Retraction Cap is elementally the same to Excellent Solid Retraction cap (K100245) Such as principles of operation. function, material, characteristic and intended use but connection shape is different depend on abutment shape	

<b>Part Name</b>	<b>Proposed Device</b>	<b>Predicate Device</b>
	<b>US Multi Angled Abutment</b>	<b>Multi Angled Abutment</b>
<b>510K</b>	-	K132067
<b>Material</b>	titanium alloy (ASTM F 136)	titanium alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	If a few number of fixture were implanted in mandibular bone for making full denture, some of fixture path should be leaned. In that case, US Multi Angled	If a few number of fixture were implanted in mandibular bone for making full denture, some of fixture path should be leaned. In that case, Multi Angled

	Abutment is used to adjust path of prosthesis.	Abutment is used to adjust path of prosthesis.
<b>Dimension (Diameter)</b>	3.4, 4.0, 4.1mm	2.84, 2.88, 3.39, 4.9mm
<b>Connection</b>	external Hex Connection	Internal Hex Connection
<b>Characteristic</b>	Screw retained restoration. Connected with Cylinder Abutment + Screw	Screw retained restoration. Connected with Cylinder Abutment + Screw
<b>Design</b>		
<b>Principles of operation</b>	US Multi Angled Abutment is connected implanted fixture and upper part is connected cylinder	Multi Angled Abutment is connected implanted fixture and upper part is connected cylinder
<b>S E</b>	<p>Difference: US Multi Angled Abutment has different connection structure connected implanted fixture from Predicate device, Multi Angled Abutment (K132067) because US Multi Angled Abutment is connected with external Hex Connection fixture and Multi Angled Abutment is connected with Internal Hex Connection fixture</p> <p>But elementally US Multi Angled Abutment and Predicate devices have same principles of operation, function, material, Connection structure connected with cylinder, characteristic and intended use</p>	

<b>Part Name</b>	<b>Proposed Device</b>	<b>Predicate Device</b>
	Ti Screw	Ti Screw
<b>510K</b>	-	K062030
<b>Material</b>	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Used to connect abutment with fixture	Used to connect abutment with fixture
<b>Principles of Operation</b>	Connect an abutment with fixture using by screw	Connect an abutment with fixture using by screw
<b>Dimension (Diameter)</b>	2.2mm, 2.3mm	2.5mm, 2.6mm, 2.9mm, 3.2mm
<b>Characteristic</b>	Connect an abutment with fixture using by screw	Connect an abutment with fixture

<b>Design</b>		
<b>S E</b>	<p>Difference:                  Dimensions are different between proposed device and predicate device.</p> <p>But elementally Ti screw and Predicate devices have same principles of operation, function, material, characteristic and intended use.</p>	

Part Name	Proposed Device	Predicate Device
	Esthetic-low Temporary Cylinder	Esthetic-low Temporary Cylinder
<b>510K</b>	-	K062030
<b>Material</b>	Titanium (ASTM F 67)	Titanium (ASTM F 67)
<b>Manufacturer</b>	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.
<b>Description (Intended for use)</b>	Esthetic-low Temporary Cylinder is used for prosthetic restoration. This is used to make temporary prosthesis and designed to minimized indication constraints	Esthetic-low Temporary Cylinder is used for prosthetic restoration. This is used to make temporary prosthesis and designed to minimized indication constraints
<b>Dimension (Diameter)</b>	4.8, 5.5mm	4.8, 5.5mm
<b>Connection</b>	external Hex Connection	external Hex Connection
<b>Characteristic</b>	Cement retained restoration. Abutment + Screw	Cement retained restoration. Abutment + Screw
<b>Principles of operation</b>	Esthetic-low Temporary Cylinder is used in producing temporary prosthetics that is connected with Esthetic-low Abutment for immediate loading	Esthetic-low Temporary Cylinder is used in producing temporary prosthetics that is connected with Esthetic-low Abutment for immediate loading
<b>Design</b>		

<b>S E</b>	<p>Difference: Post shape of subject device is different with predicate Addition of new post shape</p> <p>Esthetic-low Temporary Cylinder is exactly same with predicated device, Esthetic-low Temporary Cylinder in principles of operation, function, material, Connection structure, characteristic and intended use</p>
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7. Summary of nonclinical testing:

The following nonclinical testing data were provided or relied upon in support of the substantial equivalence determination.

**Biocompatibility**

Material in use, manufacturing process, surface treatment, and sterilization method is same as the predicates, US System, OSSTEM IMPLANT CO., LTD., K062030; TS Implant System, OSSTEM IMPLANT CO., LTD., K121585; HS, HG Prosthetic System, OSSTEM IMPLANT CO., LTD., K100245; ET Prosthetic System, OSSTEM IMPLANT CO., LTD., K130662; SS System, OSSTEM IMPLANT CO., LTD., K062051; US, SS, GS System, OSSTEM IMPLANT CO., LTD., K073247; NP Cast Abutment System, OSSTEM IMPLANT CO., LTD., K121843; HU, HS, HG Prosthetic System, OSSTEM IMPLANT CO., LTD., K081575; and Multi Angled Abutment with carrier, OSSTEM IMPLANT CO., LTD., K132067. Therefore, no additional testing is required to support the biological safety of the subject devices.

**Sterilization Validation**

For Cover Screw and Healing Abutment, the test result is considered to be substantial equivalent to that of the predicate, GSII RBM Fixture of GS Fixture System, OSSTEM IMPLANT CO., LTD., K072896; therefore, no additional testing is required. Except for them, the rest are non-sterile devices and are conducted of steam sterilization validation according to ISO 17665-1:2006.

**Fatigue Test**

Fatigue testing was considered 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.

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



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Section 003

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on the information provided in this premarket notification OSSTEM CO., LTD. concludes that ET US SS Prosthetic system is substantially equivalent to the predicate devices as described herein.