**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

May 22, 2017

OSSTEM Implant Co., Ltd.
c/o Mr. David Kim
Manager
HiOSSEN Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K161689
Trade/Device Name: OSSTEM Implant System - Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 21, 2017
Received: April 21, 2017

Dear Mr. 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,


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

# Indications for Use Statement

510(k) Number K 161689

Device Name: OSSTEM Implant System - Abutment

Indication for use:
The OSSTEM Implant System - Abutment 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)

# 510(k) Summary

1. Date: May 19, 2017

| | |
|---|---|
| - Submitter's Name: | OSSTEM Implant Co., Ltd. |
| - Address: | 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, 48002 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: | DAVID KIM |
| - Phone: | 267 759 7031 |

2. Device:

| | |
|---|---|
| Trade or (Proprietary) Name: | OSSTEM Implant System - Abutment |
| Common or usual name: | Dental Abutment |
| Classification Name: | Endosseous dental implant abutment |
| Regulation Number: | 21CFR872.3630 |
| Device Classification: | Class II |
| Subsequent Product Code: | NHA |

3. Predicate Device:

Substantial equivalence is claimed to the following devices:

Primary Predicate
K130662, ET Prosthetic System, OSSTEM IMPLANT CO., LTD

Reference predicate
K120847, ET SS Implant System, OSSTEM IMPLANT CO., LTD
K081786, Ziocera & Convertible System, OSSTEM IMPLANT CO., LTD
K121585, TS Implant System, OSSTEM IMPLANT CO., LTD
K063861, GS System, OSSTEM IMPLANT CO., LTD
K110308, Prosthrtic System
K100245, HS, HG Prosthetic System
K140507, Hiossen Prosthetic system
K062051, SS System

4. Description:

The OSSTEM Implant System - Abutment is intended for use as an aid in prosthetic restoration. It consists of Abutments, components and Abutment Screws.

The OSSTEM Implant System - Abutment 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 OSSTEM Implant System - Abutment is substantially equivalent in design, function and intended use to the Predicate Devices as above.

This submission includes straight abutments only that are not intended for any divergence/implant body angulation correction. The abutments are to be used with the TS SA Fixtures cleared in K121995.

| Items | Content | |
|---|---|---|
| 1) Transfer Abutment | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 4.6, 5.0, 6.0, 7.0 |
| | Length(mm) | 7.5, 8.5, 9, 9.1, 9.5, 10, 10.1, 10.5, 10.6, 11, 11.1, 11.5, 11.6, 12, 12.1, 12.5, 12.6, 13, 13.1, 13.5, 13.6, 14, 14.5, 14.6 |
| | Angulation | - |
| | Device Description | Used for making general cement-type prosthesis. |
| 2) ZioCera Abutment | Material | Zirconia |
| | Diameter (mm) | 4.5, 5.5, 6.5 |
| | Length(mm) | 12.3, 12.7, 12.75, 13, 14.2, 14.4, 14.5, 14.75, 14.8 |
| | Angulation | - |
| | Device Description | Used for making general cement-type prosthesis. |
| 3) Quick Temporary Abutment | Material | Titanium Alloy(Ti-6Al-4V) + PEEK (Polyetherethereketone) |
| | Diameter (mm) | 4, 4.5 |
| | Length(mm) | 11.5 |
| | Angulation | - |
| | Device Description | Used temporary until final prosthesis is made. |
| 4) FreeForm ST Abutment | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 4.0, 5.0, 5.5, 6.0, 7.0 |
| | Length(mm) | 14, 14.5, 14.6 |
| | Angulation | - |
| | Device Description | Used for making general cement-type prosthesis. Used when an abutment's path must be altered or a prosthetic's margin area must be customized. |
| 5) Multi Abutment | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 4.8 |
| | Length(mm) | 8.3,8.7, 9.3, 9.7, 10.3, 10.7, 11.3, 11.7, 12.3, 12.7 |
| | Angulation | - |
| | Device Description | Used for edentulous mandible or maxilla to make full denture. |

| | | |
|---|---|---|
| 6) Stud Abutment | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 3.5 |
| | Length(mm) | 9.35, 9.75, 10.35, 10.75, 11.35, 11.75, 12.35, 12.75, 13.35, 13.75, 14.35, 14.75 |
| | Angulation | - |
| | Device Description | Used in creating stud type overdenture prosthetics. |
| 7) Rigid Protect Cap | Material | PC (PolyCarbonate Polymer) |
| | Diameter (mm) | 4.4, 5.0, 5.5, 6.6, 7.4 |
| | Length(mm) | 5.5, 5.7, 5.8, 5.9, 7.0, 7.2, 7.3, 8.5, 8.7, 8.8 |
| | Angulation | - |
| | Device Description | Used for the protection of the Rigid Abutment in the oral cavity. |
| 8) Rigid Retraction Cap | Material | POM (Polyoxymethylene) |
| | Diameter (mm) | 4.8, 6.0, 6.6, 7.7, 8.7 |
| | Length(mm) | 5.5, 7.0, 8.5 |
| | Angulation | - |
| | Device Description | Used for the protection of the Rigid Abutment on the oral cavity. |
| 9) Custom Healing Abutment | Material | PEEK ( Polyetherethereketone) |
| | Diameter (mm) | 7.05 |
| | Length(mm) | 7, 7.5, 9, 9.5, 11, 11.5 |
| | Angulation | - |
| | Device Description | Used to make a soft tissue shape before setting up prosthetics. |
| 10) Rigid Abutment | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 4.0, 4.6, 5.0, 6.0, 7.0 |
| | Length(mm) | 10, 10.4, 11, 11.4, 11.5, 11.9, 12, 12.4, 12.5, 12.9, 13, 13.4, 13.5, 13.9, 14, 14.4, 14.5, 14.9, 15, 15.4, 15.5, 15.9, 16, 16.4, 17, 17.4 |
| | Angulation | - |
| | Device Description | Used for marking general cement-type prosthesis. |
| 11) Temporary Abutment | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 4.0, 4.5 |
| | Length(mm) | 13, 13.5, 13.6, 15, 15.5, 15.6 |
| | Angulation | - |
| | Device Description | Used for temporary until final prosthesis is made. |
| 12) O-ring Retainer Cap Set | Material | Titanium + Acrylonitrile & Butadiene Polymer |
| | Diameter (mm) | Retainer Cap: 5/ O-Ring: 4.6mm |
| | Length(mm) | Retainer Cap: 3.9/ O-Ring: 1.5mm |
| | Angulation | - |
| | Device Description | Used for making stud-type overdenture.<br>Retainer Cap + O-ring |
| 13) O-ring Retainer Set | Material | Titanium + Acrylonitrile & Butadiene Polymer |
| | Diameter (mm) | Retainer: 5/ O-Ring: 4.6mm |
| | Length(mm) | Retainer: 2/ O-Ring: 1.5mm |

| | | |
|---|---|---|
| | Angulation | - |
| | Device Description | Used for making stud-type overdenture. Retainer + O-ring |
| 14) O-ring Set | Material | Acrylonitrile & Butadiene Polymer |
| | Diameter (mm) | 4.6 |
| | Length(mm) | 1.5 |
| | Angulation | - |
| | Device Description | Used for making stud-type overdenture. |
| 15) Abutment Screw | Material | Titanium Alloy (Ti-6Al-4V) |
| | Diameter (mm) | 2.0, 2.05, 2.2, 2.3, 2.5 |
| | Length(mm) | 3.35, 5.6, 7.5, 8.35, 9.6, 10.2 |
| | Angulation | - |
| | Device Description | Used to connect an abutment with fixture. |

The OSSTEM Implant System - Abutment is compatible with TS Fixture System, K121995.

TS Fixture System (TSII SA Fixture, TSIII SA Fixture, TSIII Ultra-Wide Fixture) has two types of connection, Mini type and Regular type that are same as OSSTEM Implant System - Abutment connection structure as below dimension table.

| **TS Fixture System (K121995)** | Design | Nominal Diameter | Diameter | Connection |
|---|---|---|---|---|
| **TSII SA Fixture** |  | 3.5 | 3.5mm | Mini |
| | | 4.0 | 4.2mm | Regular |
| | | 4.5 | 4.4mm | Regular |
| | | 5.0 | 4.9mm | Regular |
| **TSIII SA Fixture** |  | 3.5 | 3.75mm, 3.77mm | Mini |
| | | 4.0 | 4.2mm, 4.25mm | Regular |
| | | 4.5 | 4.6mm, 4.63mm, 4.65mm | Regular |
| | | 5.0 | 5.05mm, 5.08mm, 5.1mm | Regular |
| **TSIII SA Ultra-Wide Fixture** |  | 6.0 | 5.92mm, 5.95mm, 6.0mm | Regular |
| | | 7.0 | 6.8mm | Regular |

5. Indications for Use:

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

6. Substantial Equivalence Matrix:

Proposed devices in the this submission were all predicated by 510(k); therefore, indication for use, shape, connection structure, material, surface treatment, manufacturer and etc. are

the same with predicated devices except dimension of additional products and new compatibility with TS SA Fixtures – K121995.

Refer to the difference of additional products for detail as below table.

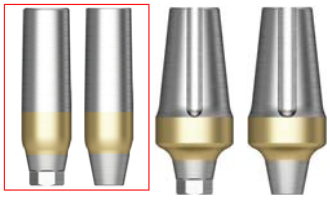
**- Substantial Equivalence Matrix**

| Part Name | ZioCera Abutment | ZioCera Abutment | Identity |
|---|---|---|---|
| | **Proposed** | **Predicate** | |
| **510K** | - | K081786 | |
| **Material** | Zirconia | Zirconia | Identical |
| **Design** |  |  | Connection structure is different (Hex and Non-Hex) but Design is Substantial Equivalence |
| **Dimension Diameter (mm)** | 4.5, 5.5, 6.5 | 4.5, 5.5, 6.5 | Diameter is identical |
| **Length of post (mm)** | **7** | **7** | Identical |
| **Indication for use** | **The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.** | **Ziocera & Convertible Systems are intended for use as an aid in prosthetic restoration.** | Indication for use of subject device is slight differences in phrase with predicate but fundamental Indication is same |
| **Technological Characteristics** | Use for making general cement-type prosthesis. | Use for making general cement-type prosthesis. | Identical |
| **S E** | ZioCera Abutment has cleared with K081786, Ziocera & Convertible System. Therefore ZioCera Abutment is resubmitted to add Hex type ZioCera Abutment<br>Proposed ZioCera Abutment are exactly same with predicate ZioCera abutment except connection structure (diameter and Length of post are also same)<br>We state ZioCera Abutment is substantial Equivalence from predicate, ZioCera Abutment (K081786) | | |
| | | | |

| Part Name | Proposed Device | Predicate Device | Identity |
|---|---|---|---|
| | Quick Temporary Abutment | Quick Temporary Abutment | |
| **510K** | - | K121585 | |
| **Material** | Titanium Alloy<br>PEEK | Titanium Alloy<br>PEEK | Identical |

| | | | |
|---|---|---|---|
| **Manufacturer** | OSSTEM Implant Co., Ltd. | OSSTEM Implant Co., Ltd. | Identical |
| **Description (Intended for use)** | used to make temporary prosthesis | used to make temporary prosthesis | Identical |
| **Dimension (Diameter)** | 4mm, 4.5mm | 4.5mm, 5.5mm | Diameter 4.0mm is added |
| **Connection** | Internal Hex Connection | Internal Hex Connection | Identical |
| **Technological Characteristics** | Cement retained restoration.<br>Capable of altering/removing shape of plastic material.<br>Two piece (Abutment + Screw) | Cement retained restoration.<br>Capable of altering/removing shape of plastic material.<br>Two piece (Abutment + Screw) | Identical |
| **Indication for use** | **The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.** | The TS Implant System is indicated 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. **The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.** | Phrase highlighted Is Identical |
| **Design** |  |  | Shape of Plastic section (PEEK) is different. Connection structure is same |
| **S E** | The Quick Temporary Abutment had been cleared with K121585 but it is being resubmitted to add revised shape therefore Quick Temporary Abutment and Predicate devices have same function, material, Connection structure, characteristic and intended use<br>We state Quick Temporary Abutment is substantial Equivalence from predicate, Quick Temporary Abutment (K121585). | | |

| **Part Name** | **Proposed Device** | **Predicate Device** | **Identity** |
|---|---|---|---|
| | FreeForm ST Abutment | FreeForm ST Abutment | |
| **510K** | - | K120847 | |
| **Material** | Titanium Alloy (Ti-6Al-4V), ASTM F 136 | Titanium Alloy (Ti-6Al-4V), ASTM F 136 | Identical |
| **Manufacturer** | OSSTEM Implant Co., Ltd. | OSSTEM Implant Co., Ltd. | Identical |
| **Description** | Use for the path adjustment of | Use for the path adjustment of | Identical |

| | | | |
|---|---|---|---|
| **(Intended for use)** | abutment or customization of prosthetic margin. | abutment or customization of prosthetic margin.. | |
| **Indication for use** | **The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.** | The ET/SS Implant System is indicated 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. **The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.** | Phrase highlighted Is Identical |
| **Technological Characteristics** | Use for making general cement-type prosthesis. | Use for making general cement-type prosthesis. | Identical |
| **Dimension (Diameter)** | 5 | 4.0, 5.0, 5.5, 6.0, 7.0 | Diameter 5mm is included dimension range of predicate |
| **Lenth of post (mm)** | 9, 10.5 | 9, 10.5 | Identical |
| **Connection** | Internal Hex Connection | Internal Hex Connection | Identical |
| **Design** |  |  | Design is Substantial Equivalence With highlighted predicate with red Box |
| **S E** | No changes in function and intended use<br>Diameter and length of post are also included dimension range of predicate<br>We state FreeForm ST Abutment is substantial Equivalence with predicate, FreeForm ST Abutment (K120847) | | |

| Part Name | Rigid Protect Cap | Rigid Protect Cap | Identity |
|---|---|---|---|
| | **Proposed** | **Predicate** | |
| **510K** | - | K100245 | |
| **Material** | PC (PolyCarbonate Polymer ) | PC (PolyCarbonate Polymer ) | Identical |
| **Design** |  |  | Identical |
| **Dimension (Diameter)** | 4.4, 5.0, 5.5, 6.6, 7.4 | 4.4, 5.0, 5.4, 6.6, 7.4 | 5.4mm diameter is changed to 5.5mm |

| | | | |
|---|---|---|---|
| **Intended for use** | Use for the protection of the rigid abutment in the oral cavity | Use for the protection of the rigid abutment in the oral cavity | Identical |
| **S.E** | No changes in function and intended use<br>Rigid Protect Cap is substantial Equivalence with predicate, Rigid Protect Cap | | |

| **Part Name** | **Multi Abutment** | **Multi Abutment** | **Identity** |
|---|---|---|---|
| | **Proposed** | **Predicate** | |
| **510K** | - | K130662 | |
| **Material** | Titanium Alloy (TiN coating) | Titanium Alloy (TiN coating) | Identical |
| **Design** |  |  | Identical |
| **Dimension (Diameter)** | 4.8 | 4.8 | Identical |
| **Intended for use** | Using for edentulous mandible or maxilla.<br>Usually use to make full denture<br>Screw Retained Restoration | Using for edentulous mandible or maxilla.<br>Usually use to make full denture<br>Screw Retained Restoration | Identical |
| **S.E** | No changes in function and intended use<br>Therefore Multi Abutment is substantial Equivalence with predicate, Multi Abutment | | |

| **Product name** | **Identity** |
|---|---|
| Transfer Abutment | - Transfer Abutment has cleared with K130662<br>- Only article numbering change.<br>- No other modifications (e.g. coating changes, design changes, addition of other models, etc.) |
| Stud Abutment | - Stud Abutment has cleared with K110308.<br>- Only article numbering change.<br>- No other modifications (e.g. coating changes, design changes, addition of other models, etc.) |
| Rigid Retraction Cap | - Rigid Retraction Cap has cleared with K100245.<br>- Only article numbering change.<br>- No other modifications (e.g. design changes, addition of other models, etc.) |
| Custom Healing Abutment | - Custom Healing Abutment has cleared with K140507.<br>- Only article numbering change.<br>- No other modifications (e.g. design changes, addition of other models, etc.) |

| | |
|---|---|
| Rigid Abutment | - Rigid Abutment has cleared with K130662.<br>- Only article numbering change.<br>- No other modifications (e.g. coating changes, design changes, addition of other models, etc.) |
| Temporary Abutment | - Temporary Abutment has cleared with K110308.<br>- Only article numbering change.<br>- No other modifications (e.g. coating changes, design changes, addition of other models, etc.) |
| O-ring Retainer Cap Set<br>O-ring Retainer Set<br>O-ring Set | - O-ring Retainer Cap Set, O-ring Retainer Set and O-ring Set has cleared with K140507.<br>- Only article numbering change.<br>- No other modifications (e.g. coating changes, design changes, addition of other models, etc.) |
| Abutment Screw | - The Abutment Screw has a cleared with 510(k), K110308 and K081786.<br>- Only article numbering change.<br>- No other modifications (e.g. coating changes, design changes, addition of other models, etc.) |

7. Summary of nonclinical testing:

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

Biocompatibility
As the material of construction, manufacturing process, chemical composition, and body contact are same as the predicate devices, ET Prosthetic System, OSSTEM Implant Co., Ltd., K130662; ET SS Implant System, OSSTEM Implant Co., Ltd., K120847; Ziocera & Convertible System, OSSTEM Implant Co., Ltd., K081786; TS Implant System, OSSTEM Implant Co., Ltd., K121585; GS System, OSSTEM Implant Co., Ltd., K063861; Prosthetic System, K110308; HS, HG Prosthetic System, K100245; and Hiossen Prosthetic System, K140507. Therefore, no additional testing is necessary. .

Sterilization Validation
For Custom Healing Abutment, it is same in material, dimension, and manufacturer with predicated Custom Healing Abutment in Hiossen Prosthetic System, K140507; and result of the sterilization validation report is leveraged that was conducted according to ISO 11137-1, ISO 11137-2 and ISO 11137-3, as well as the shelf life testing which was leveraged from K062051: tensile test (ASTM F882), seal peel test (ASTM F88/EN868-5), burst test (ASTM F1140), dye penetration (ASTM F1929), bubble test (ASTM F2096), and sterility testing (ISO 11737-2). Therefore, no additional testing is required.

Except for Custom Healing Abutment, the rest are non-sterile devices and steam sterilization validation was conducted according to ISO 17665-1 and ISO 17665-2.

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 CO., LTD. concludes that OSSTEM Implant System - Abutment is substantially equivalent to the predicate devices as described herein.