July 12, 2019

Osstem Implant Co., Ltd.
℅ Peter Lee
QA/RA Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K182091
Trade/Device Name: Osstem Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 12, 2019
Received: June 13, 2019

Dear Peter Lee:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

OSSTEM Implant Co., Ltd.
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Tel: +82 51 850 2500 Fax: +82 51 861 4693 www.osstem.com

510(k) Number: K182091

Device Name: Osstem Abutment System

Indication for Use:

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

• Link Abutment for CEREC
The Link Abutment for CEREC is titanium alloy abutments placed onto OSSTEM dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.

[X] Prescription Use (21 CFR 801 Subpart D) [ ] Over-The Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OSSTEM Implant Co., Ltd.

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Tel: +82 51 850 2500 Fax: +82 51 861 4693 www.osstem.com

510(k) Summary **K182091**

Date: July 12, 2019

1. Administrative Information

Submitter	OSSTEM IMPLANT Co., Ltd.
- Address	66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, 612-070, Korea
- Contact	Ms. Jungmin Yoo
- Phone	+82-51-850-2575
Correspondent	HIOSSEN Inc.
- Address	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact	Mr. Peter Lee
- Phone	267-759-7031

2. Device Name and Classification

Trade or (Propreitary) Name	Osstem Abutment System
Common or Usual Name	Dental Abutment
Classification Name	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Device Classification	Class II
Product Code	NHA

3. Predicate Device

Primary Predicate	
K161689	OSSTEM Implant System - Abutment, Osstem Implant Co., Ltd.
Reference Predicates	
K160670	ET US SS Prosthetic System
K160519	Link Abutment for CEREC, Osstem Implant Co., Ltd.
K150295	LOCATOR RTx, Zest Anchors, Inc.
K140507	Hiossen Prosthetic System, Osstem Implant Co., Ltd.
K132067	Multi Angled Abutment System, Osstem Implant Co., Ltd.
K120847	ET/SS Implant System, Osstem Implant Co., Ltd.
K080594	MS System (Narrow Ridge), Osstem Implant Co., Ltd.
K063861	GS System, Osstem Implant Co., Ltd.
K062030	US System, Osstem Implant Co., Ltd.

4. Indication for Use

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

• Link Abutment for CEREC
The Link Abutment for CEREC is titanium alloy abutments placed onto OSSTEM dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.

5. Device Description

Osstem Abutment System is compatible with the following implant systems.

Manufacturer	**Model Name**	**Connection**	**Diameter (mm)**
Osstem Implant Co., Ltd.	TS SA Fixture	Internal Hex	3.2, 3.5, 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.8, 4.9, 5.05, 5.08, 5.1, 5.25, 5.92, 5.95, 6, 6.2, 6.8, 7.1
	SS SA Fixture	Internal Octa	3.75, 4.1, 4.25, 4.45, 4.6, 4.9, 5, 5.05, 5.92, 5.95, 5.96, 6, 6.8, 6.93
	US SA Fixture	External Hex	3.6, 4.2, 5.1, 5.2
	MS SA Implant	Narrow Ridge	2.5, 2.9

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

Osstem Abutment System is similar to other commercially available products based on the intended use, technology used, claims, material composition employed and performance characteristics.

Osstem Abutment System is substantially equivalent in design, function and intended use to the predicate devices as above.

Device	**Content**	
Transfer Abutment	Description	Transfer Abutment is used for prosthetic restoration. It

		is used for making general cement-type prosthesis.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.0, 4.6, 5.0, 6.0, 7.0
	Post Height (mm)	4.0, 5.5, 7.0
Angled Abutment	Description	Angled Abutment is used for prosthetic restoration. It is used for making general cement-type prosthesis. It is used when a prosthetic's path adjustment is necessary
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.0, 4.5, 5.0, 6.0
	Post Height (mm)	8
	Angulation	17°
Link Abutment for Cerec	Description	Link Abutment for Cerec is used for customized prosthetic restoration. It is indicated for screw-retained single tooth or cement-retained single tooth and bridges restorations. It is compatible with the Sirona CEREC MC X and MC XL prosthetic milling system.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.5
	Post Height (mm)	4.7
Temporary Abutment	Description	Temporary Abutment is used for prosthetic restoration. It is used temporarily to maintain esthetic appearance until final prosthesis is made.
	Material	Titanium Gr.3 (ASTM F67)
	Diameter (mm)	4.0, 4.5
	G/H (mm)	1.0, 3.0
Multi Angled Abutment	Description	If a few numbers of fixtures were implanted in mandibular bone for making full denture, some of fixture path should be leaned. Multi Angled Abutment is used to adjust path of prosthesis.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.9
	Height (mm)	5, 5.1, 5.5, 5.6, 6, 6.1, 6.5, 6.6, 7.5, 7.6
	Angulation	17°, 30°
Multi NP-Cast Cylinder	Description	Multi NP-Cast Cylinder is used for prosthetic restoration. It is used for making screw-retained type prosthesis by casting with non-precious metal alloy; and used with Multi Abutment together. It creates framework of the final prosthesis to be fixed on top of the abutment.
	Material	Co-Cr-Mo Alloy (Cylinder Body) + POM (Cylinder Sleeve)
	Diameter (mm)	5.0
	Length (mm)	7.3
Multi Combination Cylinder	Description	Multi Combination Cylinder is used for prosthetic restoration. It is used for making combination-retained type prosthesis with using Multi Abutment together. It creates framework of the final prosthesis to be fixed on

		tope of the abutment.
	Material	Titanium Gr. 3 (ASTM F67)
	Diameter (mm)	5.0
	Length (mm)	7.3
Convertible Angled Cylinder	Description	Convertible Angled Cylinder is used for prosthetic restoration. It is used for making combination-retaiend type prosthesis by using with Convertible Abutment together. It is used when path adjustment is necessary at 17° axial angle.
	Material	Titanium Gr. 3 (ASTM F67)
	Diameter (mm)	4.2, 5.0, 6.3
	Length (mm)	7.8
	Angulation	17°
Stud Abutment	Description	Stud Abutment is used for prosthetic restoration. It is used for making stud type overdenture prosthetics.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	3.5
	Head length (mm)	2.5
O-ring	Description	O-ring is inserted into retainer or retainer cap and serves as a buffer for abutments/implants and denture fixation.
	Material	NBR (Acrylonitrile & Butadiene Polymer)
	Diameter (mm)	3.5
O-ring Retainer Cap	Description	O-ring Retainer Cap is used for making stud-type overdenture. It is inserted and fixed into denture; and is connected with abutment/implants.
	Material	Titanium Gr. 3 (ASTM F67)
	Diameter (mm)	3.95
	Height (mm)	2.9
Port Abutment	Description	Port Abutment is used for prosthetic restoration. It is for implant retained overdenture at maxilla/mandible in case of the patient has no teeth.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	3.5, 3.7, 4.1, 4.8, 5.1
	G/H (mm)	1, 2, 3, 4, 5, 6, 7
Port Angled Abutment	Description	Port Angled Abutment is used for prosthetic restoration. It is for implant retained overdenture needed of path compensation at maxilla/mandible in case of the patient has no teeth.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.63, 4.66, 4.68, 4.72, 4.73, 4.74, 4.77, 4.82
	Height (mm)	6.5, 6.8, 7.5, 7.6
	Angulation	10°, 17°, 30°
Port Angled Abutment Head	Description	Port Angled Abutment Head is used for prosthetic restoration. It is a part that is used to connect with Port Angled Abutment.

	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	4.6
	Height (mm)	3.7
Port Male, Port Extended Male	Description	Port Male and Port Extended Male is used for prosthetic restoration. It is used to be inserted between Port Abutment/Port Angled Abutment and Port Male Cap and takes a role to maintain retention of overdenture.
	Material	Nylon
	Diameter (mm)	4.75
	Height (mm)	1.8
Port Male Cap	Description	Port Male Cap is used for prosthetic restoration. It is used to fix Port Male or Port Extended Male by inserted into the denture.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	5.5
	Height (mm)	2.25
Port Male Kit	Description	Port Male Kit is used for prosthetic restoration by providing accessories that are used with Port Abutment or Port Angled Abutment, and it is included of Port Male Cap, Port Provisional Male, Port Spacer, and 3 different types of Port Male as a set.
	Set Configuration	Port Male Cap + Port Provisional Male + Port Spacer + Port Male (3ea)
Abutment Screw	Description	Abutment Screw is used to connect an abutment to the fixture.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	2, 2.05
	Length (mm)	7.5, 9.6
Cylinder Screw	Description	Cylinder Screw is used to connect a cylinder to the abutment.
	Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)
	Diameter (mm)	2.2, 2.5
	Length (mm)	4.35, 4.9
Esthetic-low Temporary Cylinder	Description	Esthetic-low Temporary Cylinder is used for prosthetic restoration. It is used for making temporary prosthesis before loading final prosthesis. It is used by connected with Multi Abutment, US Multi Angled Abutment or Esthetic-low Abutment to make overdenture and bridge as multiple cases.
	Material	Titanium Gr. 3 (ASTM F67)
	Diameter (mm)	4.8, 5.5
	Length (mm)	12
Temporary Cap (Narrow Ridge)	Description	Temporary Cap is used for prosthetic restoration temporarily. It is a component used to protect upper structure while final prosthesis is made.
	Material	PC (Poly Carbonate)

	Diameter (mm)	4
	Length (mm)	9.6

6. Substantial Equivalence Discussion

These subject devices are cleared in past 510(k) submissions but submitted to change their identifiers without modifications of dimensions or shape.

Link Abutment for Cerec, K160519
Multi Angled Abutment, K132067
Abutment Screw, K132067

The Indications for Use Statements are compared in the tables below. It can be seen that the Indications for Use Statements of the Subject and Primary Predicate devices are identical, with the exception of the addition to the Subject Indications for Use Statements language regarding the Link Abutment for CEREC. This language is identical to the Indications for Use Statement of the Reference Device being used for the Substantial Equivalence comparison for the Link Abutment for CEREC. All other reference devices have minor changes in wording, but nothing that affects the intended use or safety and effectiveness of the subject device system.

	Osstem Abutment System	**OSSTEM Implant System - Abutment**	**Link Abutment for CEREC**
510(k) No.	Proposed	Predicated (K161689)	Referenced (K160519)
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use Statement	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. • Link Abutment for CEREC The Link Abutment for CEREC is titanium alloy abutments placed onto OSSTEM dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned	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 Link Abutment for CEREC is titanium alloy abutments placed onto HIOSSEN dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or

	using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.		MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.

Except for them, the subject devices are substantially equivalent in indications and design principles to the predicate devices as shown below.

	Transfer Abutment	**Transfer Abutment**	**Remark**
510(k) No.	Proposed	Predicated (K161689)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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.	Identical
Principle of Operation	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Identical
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Identical

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<tr><td>5</td><td>6, 7</td><td>4, 5.5, 7</td></tr>
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<tr><td>7</td><td>1, 2, 3, 4, 5</td><td>5.5</td></tr>
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<td>-. Addition of Ø4 (<u>New, smallest diameter</u>)
-. Addition of Ø4.6 (G/H 6, 7mm)
-. Addition of Ø5 (G/H 6, 7mm)
-. Addition of Ø6 (G/H 6, 7mm)
-. Addition of Ø7 (Post 4mm)
-. Addition of Ø7 (G/H 6, 7mm)</td>
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<td>S.E.</td>
<td colspan="3">Similarities

Proposed Transfer Abutment has same design, function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is generally used for cement-retained restoration compared to that of the predicated Transfer Abutment (K161689).

Differences

The proposed Transfer Abutment has diameter of 4.0 to 7.0mm that has smallest diameter among the proposed and the predicated Transfer Abutment (K161689). However, the proposed abutment is straight type; therefore, we do not consider additional fatigue testing.

∴ Except for its size of diameter, proposed Transfer Abutment and the predicated Transfer Abutment have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Transfer Abutment is substantially equivalent to the predicated Transfer Abutment (K161689).</td>
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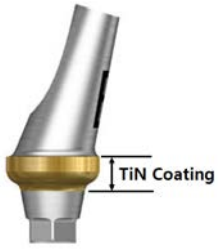
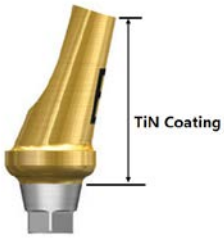
	Angled Abutment	**Angled Abutment**	**Remark**
510(k) No.	Proposed	Predicated (K120847)	**-**
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical except for its TiN coating section
Indications for Use Statement	The Osstem Abutment System is intended for use with a	The abutment is intended for use with a dental implant	Identical

	dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.	
Principle of Operation	Using making general cement-type prosthesis when a prosthetic's path adjustment is necessary.	Using making general cement-type prosthesis when a prosthetic's path adjustment is necessary.	Identical
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Identical
Diameter (mm)	4.0, 4.5, 5.0, 6.0	4.3, 4.5, 5.0, 5.5, 6.0	Ø4.0 is added; and the rest is within the range of the predicates
Post Height (mm)	8	8	Identical
Angulation	17°	17°	Identical
S.E.	**Similarities** Proposed Angled Abutment has same design, function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is generally used for cement-retained restoration compared to that of the predicated Angled Abutment (K120847). **Differences** TiN coating section between the proposed and predicated Angled Abutment is different. The proposed Angled Abutment has diameter of 4.0 to 6.0mm that has smallest diameter among the proposed and the predicated Angled Abutment (K120847). Therefore, we do consider the additional fatigue testing. ∴ While TiN coating section is changed and the devices that has different size of diameter are added, proposed Angled Abutment and the predicated Angled Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Angled Abutment is substantially equivalent to the predicated Angled Abutment (K120847).		

	Temporary Abutment	**Temporary Abutment**	**Remark**
510(k) No.	Proposed	Predicated (K161689)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical

Design			Identical except for its shape of the post
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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.	Identical
Principle of Operation	Cement/screw retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Cement/screw retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Identical
Material	Titanium Gr. 3 (ASTM F67)	Titanium Gr. 3 (ASTM F67)	Identical
Diameter (mm)	4.0, 4.5	4.0, 4.5	Identical
Post Height (mm)	10	10	Identical
S.E.	**Similarities** Proposed Temporary Abutment has same design (except for its shape of post), function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is used for cement/screw-retained restoration compared to that of the predicated Temporary Abutment (K161689). **Differences** Shape of the post between the proposed and predicated Temporary Abutment is different. Since proposed device is used temporarily, we do not consider additional fatigue testing. ∴ While shape of the post of Temporary Abutment is changed compared to the predicates, proposed Temporary Abutment and the predicated Temporary Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Temporary Abutment is substantially equivalent to the predicated Temporary Abutment (K161689).		

	Multi NP-Cast Cylinder	**Esthetic-low Gold Cylinder**	**NP-Cast Abutment**	**Remark**
510(k) No.	Proposed	Primary Predicated (K140507)	Reference Predicated (K140507)	-

Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design				Different but similar
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Hiossen Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Hiossen Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Identical
Principle of Operation	Using making screw-retained type prosthesis by casting with non-precious metal alloy; and used with Multi Abutment together by creating framework of the final prosthesis to be fixed on top of the abutment.	Using making screw-retained type prosthesis by casting with gold alloy; and used with Multi Abutment or Esthetic-low Abutment by creating framework of the final prosthesis to be fixed on top of the abutment.	Using screw-retained type prosthesis in cases with path, aesthetic, and spatial constraints by casting with non-precious metal alloy.	Similar
Material	Body: Co-Cr-Mo Alloy Sleeve: POM	Body: Gold Alloy Sleeve: POM	Body: Co-Cr-Mo Alloy Sleeve: POM	Partial Identical
Casting Material	Non-precious metal alloy	Gold alloy	Non-precious metal alloy	Different
Diameter (mm)	5.0	4.8	4.0, 4.5	Bigger than the predicates
Length (mm)	7.3	10	10	Smaller than the predicates
S.E.	**Similarities** Proposed Multi NP-Cast Cylinder has similar design that is composed with body and sleeve together; function; indications for use statement; and is used for making screw-retained restoration with Multi Abutment compared to that of the predicated Esthetic-low Gold Cylinder (K140507). **Differences** Proposed Multi NP-Cast Cylinder has bigger diameter than that of the predicated Esthetic-			

	low Gold Cylinder and NP-Cast Abutment. Also, proposed Multi NP-Cast Cylinder is being casted with non-precious metal alloy as same as the predicated NP-Cast Abutment, but the predicated Esthetic-low Gold Cylinder is being casted with gold alloy. Since the casting material in used for proposed Multi NP-Cast Cylinder has better or substantially equivalent in mechanical strength than that of the predicates; therefore, we do not consider additional fatigue testing. ∴ Proposed Multi NP-Cast Cylinder has similar design that is composed with body and sleeve together; function; and indication for use; compared to that of the predicated Esthetic-low Gold Cylinder (K140507). Therefore, the proposed Multi NP-Cast Cylinder and the predicated Esthetic-low Gold Cylinder is substantially equivalent each other.

	Multi Combination Cylinder	**Convertible Combination Cylinder**	**Remark**
510(k) No.	Proposed	Predicated (K120847)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Similar
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdenture.	Idenical
Principle of Operation	Using making combination-retained type prosthesis with using Multi Abutment together by creating framework of the final prosthesis to be fixed on top of the abutment.	Using making combination-retained type prosthesis with using Convertible Abutment together by creating framework of the final prosthesis to be fixed on tope of the abutment.	Identical
Material	Titanium Gr. 3 (ASTM F67)	Titanium Gr. 3 (ASTM F67)	Identical
Diameter (mm)	5.0	4.2 ~ 6.3	Within the range of the predicates
Length (mm)	7.3	7	Different but similar
S.E.	**Similarities** Proposed Multi Combination Cylinder has similar design, function, and indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is used for making combination-retained restoration with Multi Abutment compared to that of the predicated Convertible Combination Cylinder (K120847).		

	Differences Dimension between the proposed Multi Combination Cylinder and the predicated Convertible Combination Cylinder is different. However, proposed Multi Combination Cylinder has diameter that has within the range of the predicates; and it is a straight type cylinder; so, so we do not consider additional fatigue testing. ∴ Proposed Multi Combination Cylinder has similar design, function, and indication for use; and is casting with same material to make final prosthesis compared to that of the predicated Convertible Combination Cylinder (K120847). Therefore, the proposed Multi Combination Cylinder and the predicated Convertible Combination Cylinder is substantially equivalent each other.

	Convertible Angled Cylinder	Convertible Angled Cylinder	Remark
510(k) No.	Proposed	Predicated (K063861)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical except for TiN coating on its surface
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	GS 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 overdentrue restorations, and terminal or intermediate abutment support for fixed bridgework. GS System is for one stage surgical procedures. It is not intended for immediate load.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status
Principle of Operation	Using making combination-retained type prosthesis by using with Convertible Abutment together when path adjustment is necessary.	Using making combination-retained type prosthesis by using with Convertible Abutment together when path adjustment is necessary.	Identical
Material	Titanium Gr. 3 (ASTM F67)	Titanium Gr. 3 (ASTM F67)	Identical
Surface	Non-TiN coating	TiN coating	Different
Diameter (mm)	4.2, 5.0, 6.3	4.2, 5.0, 6.3	Identical
Length (mm)	7.8	7.8	Identical
Angulation	17°	17°	Identical

Connection	Hex, Non-Hex, Octa	Hex, Octa	Identical
S.E.	**Similarities** Proposed Convertible Angled Cylinder has same design (except for its surface on TiN-coated), function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is used for making combination-retained restoration with Convertible Abutment compared to that of the predicated Convertible Angled Cylinder (K063861). **Differences** Proposed Convertible Angled Cylinder has no TiN coating on its surface while the predicates have TiN coating on its surface. Also, the proposed Convertible Angled Cylinder Non-Hex type is added. Since this Non-Hex type addition is made having same dimensions to the predicates; therefore, we do not consider additional fatigue testing. ∴ While proposed devices has non-TiN coated on its surface, proposed Convertible Angled Cylinder and the predicated Convertible Angled Cylinder have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Convertible Angled Cylinder is substantially equivalent to the predicated Convertible Angled Cylinder (K063861).		

	Stud Abutment	**Stud Abutment**	**Remark**
510(k) No.	Proposed	Predicated (K161689)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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.	Identical
Principle of Operation	Using making stud type overdenture prosthetics	Using making stud type overdenture prosthetics	Identical
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Identical
Surface	Partial TiN coated in upper	Partial TiN coated in upper	Identical

<table>
<tr>
<td>Dimension (mm)</td>
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<tr><td>D (Ø)</td><td>3.5</td></tr>
<tr><td>Body Length</td><td>6, 6.4, 7,7.4, 8, 8.4, 9, 9.4, 10,10.4, 11, 11.4</td></tr>
<tr><td>Head Diameter (Ø)</td><td>1.7</td></tr>
<tr><td>Head Length (H)</td><td>2.5</td></tr>
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</td>
<td>
<table>
<tr><td>D (Ø)</td><td>3.5</td></tr>
<tr><td>Body Length</td><td>6, 6.4, 7,7.4, 8, 8.4, 9, 9.4, 10,10.4, 11, 11.4</td></tr>
<tr><td>Head Diameter (Ø)</td><td>2.25</td></tr>
<tr><td>Head Length (H)</td><td>3.35</td></tr>
</table>
</td>
<td>-. Addition of abutments having small ball head

∴ Identical except for head diameter and head length</td>
</tr>
<tr>
<td>S.E.</td>
<td colspan="3">Similarities

Proposed Stud Abutment has same design, function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is used for making overdenture retained restoration compared to that of the predicated Stud Abutment (K161689).

Differences

Proposed Stud Abutment has shorter head length (H, in the image above) and smaller head diameter compared to that of the predicated Stud Abutment. The shorter head length of the proposed device allows space when producing overdenture. Except for this, all dimensions are exactly same. However, the proposed abutment is straight type and it does not received single load since it is used for overdenture so the load is dispersed; therefore, we do not consider additional fatigue testing.

∴ While proposed devices has shorter head length and smaller head diameter compared to that of the predicated, proposed Stud Abutment and the predicated Stud Abutment have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed Stud Abutment is substantially equivalent to the predicated Stud Abutment (K161689).</td>
</tr>
</table>

	O-ring	**O-ring**	**Remark**
510(k) No.	Proposed	Predicated (K161689)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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.	Identical

Principle of Operation	Using inserted into retainer or retainer cap and serves as a buffer for abutments/implants and denture fixation.	Using inserted into retainer or retainer cap and serves as a buffer for abutments/implants and denture fixation.	Identical
Material	NBR (Acrylonitrile & Butadiene Polymer	NBR (Acrylonitrile & Butadiene Polymer	Identical
Diameter (mm)	3.5	4.6	Different
S.E.	**Similarities** Proposed O-ring has same design, function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated O-ring (K161689). **Differences** Proposed O-ring has smaller diameter compared to the predicated O-ring. It is used with Stud Abutment that is smaller head length (proposed in this submission) together. ∴ While proposed device has smaller diameter compared to the predicated, proposed O-ring and the predicated O-ring have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed O-ring is substantially equivalent to the predicated O-ring (K161689).		

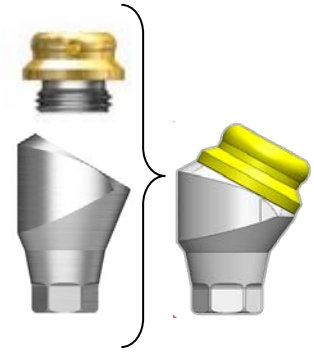
	O-ring Retainer Cap	**O-ring Retainer Cap**	**Remark**
510(k) No.	Proposed	Predicated (K161689)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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.	Identical
Principle of Operation	Using inserted and fixed into denture; and is connected with abutment/implants.	Using inserted and fixed into denture; and is connected with abutment/implants.	Identical
Material	Titanium Gr. 3 (ASTM F67)	Titanium Gr. 3 (ASTM F67)	Identical
Diameter (mm)	3.95	5	Different
Height (mm)	2.9	3.9	Different
S.E.	**Similarities**		

	Proposed O-ring Retainer Cap has same design, function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated O-ring Retainer Cap (K161689). **Differences** Proposed O-ring Retainer Cap has smaller diameter and height compared to the predicated O-ring Retainer Cap. It is used with Stud Abutment that is smaller head length (proposed in this submission) together. ∴ While proposed device has smaller diameter and length compared to the predicated, proposed O-ring Retainer Cap and the predicated O-ring Retainer Cap have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed O-ring Retainer Cap is substantially equivalent to the predicated O-ring Retainer Cap (K161689).

	Port Abutment	**LOCATOR RTx**	**Remark**
510(k) No.	Proposed	Predicated (K150295)	-
Manufacturer	Osstem Implant Co., Ltd.	Zest Anchors, Inc.	Different
Design			Similar Head part is where connected to overdenture and the screw part is where connected to the implanted fixture.
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The LOCATOR® RTx Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status.
Principle of Operation	Using making implant retained overdenture at maxilla/mandible.	Using making implant retained overdenture at maxilla/mandible.	Identical
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V ELI)	Identical
Surface	Partial TiN coated in upper	TiCN or TiN coating	Within the range of the predicates
Diameter (mm)	3.5 ~ 5.1	3.0 ~ 7.0	Within the range of the predicates

G/H (mm)	1 ~ 7	1 ~ 6	Exceed (bigger than) the range of the predicates
Abutment Angle	Straight	Straight	Identical
S.E.	**Similarities** Proposed Port Abutment design, function, indications for use statement, is made with same material and is used for making overdenture retained restoration compared to that of the predicated LOCATOR RTx (K150295). **Differences** Dimension between the proposed and the predicates are different: proposed Port Abutment has diameter range from 3.5 to 5.1 whilte the predicated LOCATOR RTx has range from 3.0 to 7.0. Also, proposed Port Abutment has G/H range from 1 to 7 while the predicated LOCATOR RTx has range from 1 to 6. Proposed Port Abutment has TiN coating on its surface while the predicated LOCATOR RTx has either TiCN or TiN coating on its surface. Proposed abutment is straight type, is intended for straight implantation, and is not received single load because this is used for making overdenture that means load is dispersed to the full denture; therefore, we do not consider additional fatigue testing. ∴ Proposed Port Abutment has similar design, function, and indication for use; and is made with same material compared to that of the predicated LOCATOR RTx (K150295). Since diameter and G/H of the proposed device are within or larger than the predicated device dimension, no additional safety and effectivencess evaluation is required. Therefore, the proposed Port Abutment and the predicated LOCATOR RTx is substantially equivalent each other.		

	Port Angled Abutment & Port Angled Abutment Head	**Multi Angled Abutment**	**LOCATOR RTx**	**Remark**
510(k) No.	Proposed	Primary Predicated (K132067)	Reference Predicated (K150295)	-
Manufacturer	Osstem Implant Co. Ltd.		Zest Anchors, LLC	Different

Design				Different
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Multi Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as bridges, or overdentures.	The LOCATOR® RTx Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status.
Principle of Operation	Using making implant retained overdenture needed of path compensation at maxilla/mandible.	Using making screw-retained type prosthesis in multiple cases by using with Esthetic-low cylinder when path adjustment is necessary.	Using for implant retained overdenture at maxilla/mandible.	Similar
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V ELI)	Identical
Diameter (mm)	4.63 ~ 4.82	4.9	3.0 ~ 7.0	Within the range of the predicates
Abutment Angle	10º/17 º/30º	17 º/30º	Straight	Different
S.E.	**Similarities** Proposed Port Angled Abutment has similar indications for use statement, design, function, abutment angle, is made with same raw material, and is used for making overdenture			

	retained restoration compared to that of the primary predicate device, Multi Angled Abutment (K132067). Proposed Port Angled Abutment has diameter which is within the range of the reference predicate device, LOCATOR RTx (K150295). **Differences** While proposed Port Angled Abutment has angle of 10, 17, and 30 degrees, the primary predicate device, Multi Angled Abutment has angle of 17 and 30 degrees; but the reference device, LOCATOR RTx is straight type abutment. Proposed Port Angled Abutment should be used connected by Port Angled Abutment Head together to place overdenture on top of the abutment but reference predicate. Since proposed Port Angled Abutment is used to make overdenture and does not receive single load because the load is dispersed to the denture; therefore, we do not consider additional fatigue testing. ∴ Proposed Port Angled Abutment has similar indication for use, design, function, abutment angle, and is made with same raw material compared to that of the primary predicate device, Multi Angled Abutment (K132067); and it has diameter that is within the range of the reference predicate device, LOCATOR RTx (K150295). Therefore, the proposed Port Angled Abutment is substantially equivalent to the predicates.

	Port Male Port Extended Male	**Retention Insert**	**Remark**
510(k) No.	Proposed	Predicated (K150295)	-
Manufacturer	Osstem Implant Co., Ltd.	Zest Anchors, Inc.	Different
Design			Similar
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The LOCATOR® RTx Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status.
Principle of Operation	Using inserted between Port Abutment/Port Angled Abutment and Port Male Cap and takes a role to maintain retention of overdenture.	Using inserted between Locator RTx and dental attachment housing and takes a role to maintain retention of overdenture.	Identical
Material	Nylon	Nylon or PEEK	Within the range of the predicates

S.E.	**Similarities** Proposed Port Male/Port Extended Male has similar design, function, indications for use statement, and is made with one of same materials compared to that of the predicated Retention Insert (K150295). **Differences** Proposed Male has 6 different types based on its retention levels while the predicated Retention Insert has simplified 4 different types based on its retention levels from zero to high. ∴ Proposed Port Male/Port Extended Male has similar design, function, and indication for use; and is made with one of same materials compared to that of the predicated Retention Insert (K150295). Therefore, the proposed Port Male/Port Extended Male and the predicated Retention Insert is substantially equivalent each other.

	Port Male Cap	Denture Attachment Housing	Remark
510(k) No.	Proposed	Predicated (K150295)	-
Manufacturer	Osstem Implant Co., Ltd.	Zest Anchors, Inc.	Different
Design			Similar
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The LOCATOR® RTx Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status.
Principle of Operation	Using fixing Port Male or Port Extended Male by inserted into the denture.	Using fixing Retention Insert by inserted into the denture.	Identical
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4 ELI)	Identical
S.E.	**Similarities** Proposed Port Male Cap has similar design, function, indications for use statement, and is made of same material compared to that of the predicated Denture Attachment Housing (K150295).		

	Differences Proposed Port Male Cap is not applied of surface treatment while the predicated Denture Attachment Housing has applied of pink anodizing on its surface. ∴ Proposed Port Male Cap has similar design, function, and indication for use; and is made with same material compared to that of the predicated Denture Attachment Housing (K150295). Therefore, the proposed Port Male Cap and the predicated Dental Attachment Housing is substantially equivalent each other.

	EbonyGold Cylinder Screw	**EbonyGold Cylinder Screw**	**Remark**
510(k) No.	Proposed	Predicated (K120847)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Identical
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.	Identical
Principle of Operation	Using to connect a cylinder to the abutment.	Using to connect a cylinder to the abutment.	Identical
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Identical
Diameter (mm)	2.2, 2.5	2.2, 2.5	Identical
Length (mm)	4.35, 4.9	4.15, 4.7	Different
S.E.	**Similarities** Proposed Abutment Screw has same design, function and indications for use statement; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated Abutment Screw (K120847). **Differences** Proposed Abutment Screw has same diameter, but longer in length compared to the predicated Abutment Screw. ∴ While proposed device has longer in length compared to the predicated, proposed Abutment Screw and the predicated Abutment Screw have common in design, function, indications for use, material, manufacturing process, manufacrurer, etc.; and the difference does not affect to safety and effectiveness of the product. Therefore, the proposed Abutment Screw is substantially equivalent to the prediated Abutment Screw (K120847).		

	Esthetic-low Temporary Cylinder	Esthetic-low Temporary Cylinder	Esthetic-low Temporary Cylinder	Remark
510(k) No.	Proposed	Predicated (K062030)	Predicated (K160670)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design				Shape of post is different
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	US system and SSII mini are 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 terminal or intermediate abutment support for fixed bridgework. US System is for two stage surgical procedures. It is not for one stage surgery or immediate load. The SSII mini is for one and two stage surgical procedures. It is not for immediate load.	The OSSTEM Prosthetic System is intended for use with a dental implant to provide support for prosthetic restoration suc h as crowns, bridges, or over-dentures.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status
Principle of Operation	Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with Multi Abutment, US Multi Angled	Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with Multi Abutment, US Multi Angled	Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with Multi Abutment, US Multi Angled	Identical

	Abutment or Esthetic-low Abutment to make overdenture and bridge as multiple cases.	Abutment or Esthetic-low Abutment to make overdenture and bridge as multiple cases.	Abutment or Esthetic-low Abutment to make overdenture and bridge as multiple cases.	
Material	Titanium Gr. 3 (ASTM F67)	Titanium Gr. 3 (ASTM F67)	Titanium Gr. 3 (ASTM F67)	Identical
Diameter (mm)	4.8, 5.5	5.3, 6.0	4.8, 5.5	Partial identical
Post Diameter (mm)	3.7, 4.1	3.8, 4.2	3.35, 3.8	Different
Length (mm)	12	12	12	Identical
Type	Standard Type	Standard Type	Narrow Type	Partial identical
Connection	External Hex	External Hex	External Hex	Identical
S.E.	**Similarities** Proposed Esthetic-low Temporary Cylinder has same connection structure, function, indications for use statement; and is made with same material with same manufacturing method by same manufacturer and is used for making screw-retained restoration compared to that of the predicated Esthetic-low Temporary Cylinder (K062030, K160670). **Differences** Proposed Esthetic-low Temporary Cylinder is standard type, has smaller diameter, same length, but different shape of post compared to that of the predicated Esthetic-low Temporary Cylinder (K062030). However, it has same shape of post, diameter, length, indication, etc., but bigger post diameter compared to that of the predicated narrow type Esthetic-low Cylinder (K160670). Since proposed device is used temporarily and does not have smallest diameter in this submission, we do not consider additional fatigue testing. ∴ While proposed device has smaller diameter, same length, but different shape of post compared to the predicated, proposed Esthetic-low Temporary Cylinder and the predicated Esthetic-low Temporary Cylinder have common in function, indications for use, material, manufacturing process, manufacturer, etc.; and the difference does not raise safety and effectiveness issue. Therefore, the proposed Esthetic-low Temporary Cylinder is substantially equivalent to the predicated Esthetic-low Temporary Cylinder (K062030, K160670).			

	Temporary Cap	**Temporary Cap**	**Remark**
510(k) No.	Proposed	Predicated (K080594)	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical

Design			Shape of post is different
Indications for Use Statement	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The MS System (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. MS System (Narrow Ridge) are intended for single use only.	The proposed device and the predicated device has different indication for use in language, however the difference in language does not change the intended use or substantial equivalence status
Principle of Operation	Using making prosthetic restoration temporarily by protecting upper structure while final prosthesis is made.	Using making prosthetic restoration temporarily by protecting upper structure while final prosthesis is made.	Identical
Material	PC (Poly Carbonate)	PC (Poly Carbonate)	Identical
Diameter (mm)	4	3.95 (4)	Identical (within its tolerance of ± 0.05)
Length (mm)	9.6	9.6	Identical
S.E.	**Similarities** Proposed Temporary Cap has same basic structure, function, indications for use statement; and is made with same material with same manufacturing method by same manufacturer compared to that of the predicated Temporary Cap (K080594). **Differences** Proposed Temporary Cap has different shape of post compared to the predicated Temporary Cap. ∴ While proposed device has different shape of post compared to the predicated, proposed Temporary Cap and the predicated Temporary Cap have common in function, indications for use, material, manufacturing process, manufacturer, etc.; and the difference does not raise safety and effectiveness issue. Therefore, the proposed Temporary Cap is substantially equivalent to the predicated Temporary Cap (K080594).		

7. Summary of Non-clinical Performance Testing

Non-clinical testing data are submitted, referenced, or relied upon to demonstrate substantial equivalence.

Biocompatibility Evaluation
Biocompatibility testing was performed following the FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*and the ISO 10993 suite of standards.

Sterilization Validation
Subject devices are provided to the market in non-sterile status, and steam sterilization validation was considered according to ISO 17665-1.

Mechanical Properties
Fatigue testing was considered according to the FDA Guidance Document *Guidance for Industry and FDA Staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment* and ISO 14801 standard with the worst case scenario. Retention testing for dental attachments was conducted.

8. Summary of Clinical Testing

No clinical studies are submitted.

9. Conclusion

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 Osstem Abutment System is substantially equivalent to the predicates devices as herein.