February 20, 2024

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

Re: K233194
Trade/Device Name: TS Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 22, 2023
Received: November 22, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233194

Device Name
TS Abutment System

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

510(k) Summary
K233194

Date: February 16, 2024

1. Company and Correspondent making the submission

- Submitter's Name : Osstem Implant Co., Ltd.
- Address : 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, 48002, Republic of Korea
- Contact : Ms. Seungju Kang
- Phone : +82-51-850-2500
- Correspondent's Name : Hiossen Inc.
- Address : 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact : Mr. Peter Lee
- Phone : +1-267-759-7031

2. Proposed Device

- Trade or (Proprietary) Name : TS Abutment System
- Classification Name : Endosseous dental implant Abutment
- Regulation Number : 21 CFR 872.3630
- Devce Classification : Class II
- Classification Product Code : NHA

3. Predicated Device

Primary Predicate	
K182091	Osstem Abutment System
Reference Device	
K221684	Osstem Abutment System
K163634	External Hex Implants
K161689	OSSTEM Implant System - Abutment
K161604	OSSTEM Implant System
K120847	ET/SS IMPLANT SYSTEM

4. Indication for use

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

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5. Device Description

TS Abutment System is made of titanium, titanium alloy. TS Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. TS Abutment System is similar to other commercially available products based on the intended use, technology used, material composition employed and performance characteristics.

The specifications of the proposed device are as follow;

<table>
<tr><th>Device</th><th colspan="2">Content</th></tr>
<tr><td rowspan="3">Rigid Abutment</td><td>Description</td><td>It is used for making general cement-type prosthesis.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>6.0, 7.0</td><td>5.5</td></tr>
<tr><td>4.6</td><td>6.0, 7.0</td><td>5.5</td></tr>
<tr><td>5.0</td><td>6.0, 7.0</td><td>4.0, 5.5</td></tr>
</table>
</td></tr>
<tr><td rowspan="3">Transfer Abutment</td><td>Description</td><td>It is used for making general cement-type prosthesis.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
</table>
</td></tr>
<tr><td rowspan="4">Angled Abutment</td><td>Description</td><td>It is used for making general cement-type prosthesis.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>2.0, 4.0</td><td>8.0</td></tr>
<tr><td>4.5</td><td>2.0, 4.0</td><td>8.0</td></tr>
<tr><td>5.0</td><td>2.0, 4.0</td><td>8.0</td></tr>
<tr><td>6.0</td><td>2.0, 4.0</td><td>8.0</td></tr>
</table>
</td></tr>
<tr><td>Angle(˚)</td><td>17</td></tr>
<tr><td rowspan="3">FreeForm ST Abutment</td><td>Description</td><td>It is used for making general cement-type prosthesis.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>5.5</td><td>1.5, 3.0</td><td>8.0</td></tr>
</table>
</td></tr>
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<table>
<tr><td rowspan="3">Temporary Abutment</td><td>Description</td><td>It is used temporarily to maintain esthetic appearance and chew ability until final prosthesis is made.</td></tr>
<tr><td>Material</td><td>Titanium Gr.3 (ASTM F67)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>7.0</td><td>10.0</td></tr><tr><td>4.5</td><td>7.0</td><td>10.0</td></tr></table></td></tr>
<tr><td rowspan="3">Multi Abutment</td><td>Description</td><td>It is used for edentulous mandible or maxilla and usually used to make full denture.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>2.3</td></tr></table></td></tr>
<tr><td rowspan="4">Multi Angled Abutment</td><td>Description</td><td>TS Multi Angled Abutment is used to adjust the path of prosthesis in the case where the path is misaligned. It is provided as a set product composed with abutment, screw, and carrier to the end users for their convienience.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.9</td><td>2.5, 3.0, 3.5, 4.0, 5.0</td><td>2.3</td></tr></table></td></tr>
<tr><td>Angle(˚)</td><td>17˚, 30˚</td></tr>
<tr><td rowspan="3">Convertible Abutment</td><td>Description</td><td>It is used for creating bridge case prosthesis with dislocated path.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0</td><td>1.0</td></tr><tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>1.2</td></tr><tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>1.2</td></tr></table></td></tr>
<tr><td rowspan="3">Ti Cylinder Screw</td><td>Description</td><td>It is used to make final prosthesis using Convertible Abutment.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>L</th></tr><tr><td>2.2</td><td>4.35</td></tr><tr><td>2.5</td><td>4.9</td></tr></table></td></tr>
<tr><td rowspan="2">Port Abutment</td><td>Description</td><td>It is used for prosthetic restoration. It is for implant retained overdenture at maxilla/mandible in case of the patient has no teeth.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
</table>

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<table>
<tr><td></td><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>3.7</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>1.5</td></tr></table></td></tr>
<tr><td rowspan="3">Stud Abutment</td><td>Description</td><td>It is used for prosthetic restoration. It is used for making stud type overdenture prosthetics.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>3.5</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0</td><td>2.5, 3.35</td></tr></table></td></tr>
<tr><td rowspan="3">Healing Abutment</td><td>Description</td><td>It is used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.</td></tr>
<tr><td>Material</td><td>Titanium Gr.4 (ASTM F67)</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>L</th></tr><tr><td>4.3</td><td>2.0, 6.0, 8.0</td></tr><tr><td>4.8</td><td>6.0, 8.0, 10.0</td></tr><tr><td>5.3</td><td>6.0, 8.0, 10.0, 11.0, 12.0</td></tr><tr><td>6.3</td><td>6.0, 8.0</td></tr><tr><td>7.3</td><td>6.0, 8.0</td></tr><tr><td>8.3</td><td>6.0, 8.0</td></tr><tr><td>9.3</td><td>5.0, 6.0, 8.0</td></tr></table></td></tr>
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6. Substantial Equivalence Matrix

These subject devices are modifications to abutments that are cleared in past 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.

1.1 Non-Sterile Device

1) Rigid Abutment

	Subject Device	Reference Device	Primary Predicate	Remark
Device Name	Rigid Abutment	Rigid Abutment	Transfer Abutment	Same
510(k) Number	-	K161689	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design				Same
Indication for Use	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.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Same

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<table>
<tr>
<td>Dimension (mm)</td>
<td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>6.0, 7.0,</td><td>5.5</td></tr>
<tr><td>4.6</td><td>6.0, 7.0</td><td>5.5</td></tr>
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<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>5.5</td></tr>
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<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5</td></tr>
</table>
</td>
<td>Different</td>
</tr>
<tr><td>Material</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="4">Similarities
Proposed Rigid Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device Rigid Abutment, K161689.

Differences
The added lengths differ from the dimension range of the reference device because new length combination is added to the same diameter range as primary predicate. However, proposed device has same design, function, connection and platform as reference device. Also, primary predicate for the increased gingival height of 6mm and 7mm is already cleared in Transfer Abutment, K182091.
In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO 14801, it has same moment arm.

As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the reference device. Therefore, we don’t conduct additional fatigue testing.</td></tr>
</table>

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	∴Proposed Rigid Abutment and the reference device have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the reference device.

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2) Transfer Abutment

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate</th><th>Remark</th></tr>
<tr><td>Device Name</td><td>Transfer Abutment</td><td>Transfer Abutment</td><td>Different</td></tr>
<tr><td>510(k) Number</td><td>-</td><td>K182091</td><td>-</td></tr>
<tr><td>Manufacturer</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Same</td></tr>
<tr><td>Design</td><td>  </td><td>  </td><td>Different</td></tr>
<tr><td>Indication for Use</td><td>The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>Using making for general cement-type prosthesis.</td><td>Using making for general cement-type prosthesis.</td><td>Same</td></tr>
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<tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5</td></tr>
</table>
</td><td>Different</td></tr>
<tr><td>Material</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Feature</td><td>  </td><td>  </td><td>Different</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="3">Similarities
Proposed Transfer Abutment has same design, function and indication for use; and is made</td></tr>
</table>

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	with same material with same manufacturing process by same manufacturer compared to that of the primary predicate Transfer Abutment, K182091. **Differences** The added lengths differ from the dimension range of the primary predicate because new length combination is added to the same diameter range as primary predicate. Also, proposed device differs in feature from the primary predicate because it has a guide to support connecting with the implant body. However, this change in connection features was evaluated and determinded that is not a new worst case for bench testing. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO 14801, it has same moment arm. As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the primary predicate. Therefore, we don't conduct additional fatigue testing. ∴ Proposed Transfer Abutment and the primary predicate have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the primary predicate.

3) Angled Abutment

	Subject Device	**Primary Predicate**	**Remark**
Device Name	Angled Abutment	Angled Abutment	Same
510(k) Number	-	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Different
Indication for Use	The 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 intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
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.	Same

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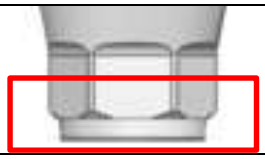
<table>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>4.5</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>5.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>6.0</td><td>2.0, 4.0</td><td>8.0</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>4.5</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>5.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>6.0</td><td>2.0, 4.0</td><td>8.0</td></tr></table></td><td>Same</td></tr>
<tr><td>Angled(˚)</td><td>17</td><td>17</td><td>Same</td></tr>
<tr><td>Material</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Feature</td><td>  </td><td>  </td><td>Different</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="3">Similarities
Proposed Angled Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate Angled Abutment, K182091.

Differences
The proposed device differs in feature from the primary predicate because it has a guide to support connecting with the implant body. However, proposed device has same design, function, connection and platform as primary predicate.

As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the primary predicate. Therefore, we don’t conduct additional fatigue testing.

∴ Proposed Angled Abutment and the primary predicate have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the primary predicate.</td></tr>
</table>

4) FreeForm ST Abutment

	Subject Device	**Reference Device**	**Remark**
Device Name	FreeForm ST Abutment	FreeForm ST Abutment	Same
510(k) Number	-	K161689	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Same

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<table>
<tr><td>Indication for Use</td><td>The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>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.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>Use for making general cement-type prosthesis.</td><td>Use for making general cement-type prosthesis.</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>5.5</td><td>1.5, 3.0</td><td>8.0</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>1.5, 3.0</td><td>9.0, 10.5</td></tr><tr><td>5.0</td><td>1.5, 3.0</td><td>9.0, 10.5</td></tr><tr><td>6.0</td><td>1.5, 3.0</td><td>9.0, 10.5</td></tr><tr><td>7.0</td><td>1.5, 3.0</td><td>9.0, 10.5</td></tr></table></td><td>Different</td></tr>
<tr><td>Material</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="3">Similarities
Proposed FreeForm ST Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device FreeForm ST Abutment, K161689.

Differences
The added diameter Ø 5.5 and length 8mm differs from reference device; but it is included in the dimension range of the reference device. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO 14801, it has same moment arm.

As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the reference device. Therefore, we don’t conduct additional fatigue testing.

∴Proposed FreeForm ST Abutment and the reference device have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the reference device.</td></tr>
</table>

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5) Temporary Abutment

	Subject Device	**Reference Device**	**Primary Predicate**	**Primary Predicate**	**Remark**
Device Name	Temporary Abutment	Temporary Abutment	Temporary Abutment	Transfer Abutment	Same
510(k) Number	-	K221684	K182091	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design					Same
Indication for Use	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 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 intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Using making for general cement-type prosthesis.	Same

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Dimension (mm)	<table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>**7.0**</td><td>10.0</td></tr><tr><td>4.5</td><td>**7.0**</td><td>10.0</td></tr></table>	<table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>1.0, 3.0</td><td>10</td></tr><tr><td>4.5</td><td>1.0, 3.0</td><td>10</td></tr></table>	<table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>1.0, 3.0</td><td>10</td></tr><tr><td>4.5</td><td>1.0, 3.0</td><td>10</td></tr></table>	<table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr><tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr><tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr><tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr><tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5</td></tr></table>	Different
Material	Titanium Gr.3 (ASTM F67)	Titanium Gr.3 (ASTM F67)	Titanium Gr.3 (ASTM F67)	Titanium Alloy (ASTM F136)	Same
Surface Treatment	N/A	N/A	N/A	N/A	Same
S.E.	**Similarities** Proposed Temporary Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device and primary predicate Temporary Abutment, K221684 and K182091. **Differences** Temporary Abutment is used to make temporary prosthesis for esthetic purpose for healing period after placement of implant, so the length of gingiva height does not affect the any performance. Also, the proposed gingiva height 7mm differs from primary predicate and reference device; but the proposed diameter is same as reference device, and primary predicate for the increased gingival height of 7mm is already cleared in Transfer Abutment, K182091.				

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	Proposed device is used for temporary use and also has primary predicate for the increased gingival height. Therefore, we don't conduct additional performance test. ∴ Proposed Temporary Abutment and the primary predicate have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the primary predicate.

6) Multi Abutment

	Subject Device	**Reference Device**	**Primary Predicate**	**Remark**
Device Name	Multi Abutment	Multi Abutment	Transfer Abutment	Same
510(k) Number	-	K161689	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design				Same
Indication for Use	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.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using for edentulous mandible or maxilla. Usually use to make full denture screw-retained restoration.	Using for edentulous mandible or maxilla. Usually use to make full denture screw-retained restoration.	Using making for general cement-type prosthesis.	Same

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<table>
<tr>
<td>Dimension (mm)</td>
<td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.8</td><td>6.0, 7.0</td><td>2.3</td></tr>
</table>
</td>
<td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>2.3</td></tr>
</table>
</td>
<td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5</td></tr>
</table>
</td>
<td>Different</td>
</tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td><td>Ti-6Al-4V (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="4">Similarities
Proposed Multi Abutment has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device Multi Abutment, K161689.

Differences
The proposed gingiva height 6mm and 7mm differ from reference device; but the proposed diameter is same as reference device, and primary predicate for the increased gingival height of 6mm and 7mm is already cleared in Transfer Abutment, K182091. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO 14801, it has same moment arm.

As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the reference device. Therefore, we don’t conduct additional fatigue testing.

∴ Proposed Multi Abutment and the reference device have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the reference device.</td></tr>
</table>

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7) Ti Cylinder Screw

	Subject Device	**Primary Predicate**	**Remark**
Device Name	Ti Cylinder Screw	EbonyGold Cylinder Screw	Same
510(k) Number	-	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Different
Indication for Use	The 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 intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using to connect a cylinder to the abutment.	Using to connect a cylinder to the abutment.	Same
Dimension (mm)	**D(Ø)** / **L** 2.2 / 4.35 2.5 / 4.9	**D(Ø)** / **L** 2.2 / 4.35 2.5 / 4.9	Same
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Same
Surface treatment	N/A	WC Coating	Different
S.E.	**Similarities** Proposed Ti Cylinder Screw has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate EbonyGold Cylinder Screw, K182091. **Differences** The only difference is surface treatment. The primary predicate has WC coating surface, but the proposed device has no surface treatment. However, since the proposed device is a component using with cylinder, we don't consider fatigue testing. In addition, the proposed device has a difference in surface coating from the primary predicate, but there is no difference in biocompatibility because it has the same raw material as the Abutments made of titanium alloy already cleared in K182091. ∴ Proposed Ti Cylinder Screw and the primary predicate have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the primary predicate.		

1.2 Sterile Device

1) Transfer Abutment

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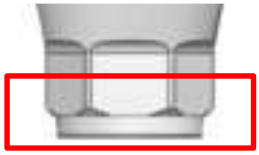
<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate</th><th>Remark</th></tr>
<tr><td>Device Name</td><td>Transfer Abutment</td><td>Transfer Abutment</td><td>Different</td></tr>
<tr><td>510(k) Number</td><td>-</td><td>K182091</td><td>-</td></tr>
<tr><td>Manufacturer</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Same</td></tr>
<tr><td>Design</td><td>  </td><td>  </td><td>Different</td></tr>
<tr><td>Indication for Use</td><td>The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>Using making for general cement-type prosthesis.</td><td>Using making for general cement-type prosthesis.</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
</table>
</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
<tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5</td></tr>
</table>
</td><td>Different</td></tr>
<tr><td>Material</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Feature</td><td>  </td><td>  </td><td>Different</td></tr>
<tr><td>Sterilization</td><td>Provided sterile
(Radiation Sterile for Identifier TSTA****WH and TSTA****TH)</td><td>Sterile by end users</td><td>Different</td></tr>
<tr><td>Shelf-life</td><td>8 years</td><td>N/A</td><td>Different</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
</table>

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S.E.	**Similarities** Proposed Transfer Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate Transfer Abutment, K182091. **Differences** The added lengths differ from the dimension range of the primary predicate because new length combination is added to the same diameter range as primary predicate. Also, proposed device differs in feature from the primary predicate because it has a guide to support connecting with the implant body. However, proposed device has same design, function, connection and platform as primary predicate. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO 14801, it has same moment arm. As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the primary predicate. Therefore, we don't conduct additional fatigue testing. Proposed device, identifier TSTA****WH and TSTA****TH, differs in sterilization process. The proposed device is sterilized compared to the primary predicate; but it has same raw material, design, manufacturing process, etc. as that of the primary predicate. ∴ Proposed Transfer Abutment and the primary predicate have common in design, function, indication for use, material, manufacturing process, manufacturer, etc., except sterilization process; therefore, the proposed device is substantially equivalent to the primary predicate.

2) Angled Abutment

	Subject Device	**Primary Predicate**	**Remark**
Device Name	Angled Abutment	Angled Abutment	Same
510(k) Number	-	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Different
Indication for Use	The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same

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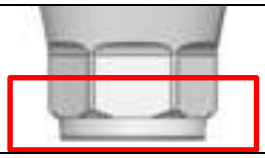
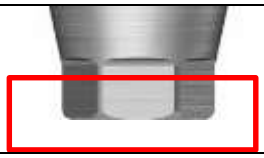
<table>
<tr><td></td><td>overdentures.</td><td></td><td></td></tr>
<tr><td>Principle of Operation</td><td>Using making general cement-type prosthesis when a prosthetic’s path adjustment is necessary.</td><td>Using making general cement-type prosthesis when a prosthetic’s path adjustment is necessary.</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>4.5</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>5.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>6.0</td><td>2.0, 4.0</td><td>8.0</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>4.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>4.5</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>5.0</td><td>2.0, 4.0</td><td>8.0</td></tr><tr><td>6.0</td><td>2.0, 4.0</td><td>8.0</td></tr></table></td><td>Same</td></tr>
<tr><td>Angled(˚)</td><td>17</td><td>17</td><td>Same</td></tr>
<tr><td>Material</td><td>Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same</td></tr>
<tr><td>Feature</td><td>  </td><td>  </td><td>Different</td></tr>
<tr><td>Sterilization</td><td>Provided sterile
(Radiation Sterile for Identifier TSAA****WH and TSAA****TH)</td><td>Sterile by end users</td><td>Different</td></tr>
<tr><td>Shelf-life</td><td>8 years</td><td>N/A</td><td>Different</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="3">Similarities
Proposed Angled Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate Angled Abutment, K182091.

Differences
The only difference is sterilization process. The proposed device is sterilized compared to the primary predicate; but it has same raw material, design, manufacturing process, etc. as that of the primary predicate.

∴ Proposed Angled Abutment and the primary predicate have common in design, function, indication for use, material, manufacturing process, manufacturer, etc., except sterilization process; therefore, the proposed device is substantially equivalent to the primary predicate.</td></tr>
</table>

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3) Multi Abutment

<table>
<tr><th></th><th>Subject Device</th><th>Reference Device</th><th>Primary Predicate</th><th>Remark</th></tr>
<tr><td>Device Name</td><td>Multi Abutment</td><td>Multi Abutment</td><td>Transfer Abutment</td><td>Same</td></tr>
<tr><td>510(k) Number</td><td>-</td><td>K161689</td><td>K182091</td><td>-</td></tr>
<tr><td>Manufacturer</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Same</td></tr>
<tr><td>Design</td><td>  </td><td>  </td><td>  </td><td>Same</td></tr>
<tr><td>Indication for Use</td><td>The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>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.</td><td>Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>Using for edentulous mandible or maxilla. Usually use to make full denture screw-retained restoration.</td><td>Using for edentulous mandible or maxilla. Usually use to make full denture screw-retained restoration.</td><td>Using making for general cement-type prosthesis.</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>2.3</td></tr>
</table>
</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>2.3</td></tr>
</table>
</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>4.6</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>5.5, 7.0</td></tr>
<tr><td>5.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr>
</table>
</td><td>Different</td></tr>
</table>

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			<table><tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5, 7.0</td></tr><tr><td>7.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0</td><td>4.0, 5.5</td></tr></table>	
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Titanium Alloy (ASTM F136)	Same
Sterilization	Provided sterile (Radiation Sterile for Identifier TSMA****SP)	Sterile by end users	Sterile by end users	Different
Shelf-life	8 years	N/A	N/A	Different
Surface Treatment	N/A	N/A	N/A	Same
S.E.	**Similarities** Proposed Multi Abutment has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device Multi Abutment, K221684 and K182091. **Differences** The proposed gingiva height 6mm and 7mm differ from reference device; but the proposed diameter is same as reference device, and primary predicate for the increased gingival height of 6mm and 7mm is already cleared in Transfer Abutment, K182091. In addition, since proposed device is straight type and the distance between the embedding plane and the centre of the hemispherical loading member always is 11mm according to the ISO 14801, it has same moment arm. As a result, the fatigue of the proposed device is considered to be equal to or greater than that of the reference device. Therefore, we don't conduct additional fatigue testing. Proposed device, identifier TSMA****SP, differs in sterilization process. The proposed device is sterilized compared to the reference device; but it has same raw material, design, manufacturing process, etc. as that of the reference device. ∴ Proposed Multi Abutment and the reference device have common in design, function, indication for use, material, manufacturing process, manufacturer, etc. except sterilization process; therefore, the proposed device is substantially equivalent to the reference device.			

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4) Multi Angled Abutment

	Subject Device	**Reference Device**	**Primary Predicate**	**Remark**
Device Name	Multi Angled Abutment	Multi Angled Abutment	Multi Angled Abutment	Same
510(k) Number	-	K221684	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design				Same
Indication for Use	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 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 intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using making screw-retained type prosthesis in multiple cases by using with Esthetic-low cylinder when path adjustment is necessary.	Using making screw-retained type prosthesis in multiple cases by using with Esthetic-low cylinder when path adjustment is necessary.	Using making screw-retained type prosthesis in multiple cases by using with Esthetic-low cylinder when path adjustment is necessary.	Same
Dimension (mm)	**D(Ø)** / **G/H** / **Post** 4.9 / 2.5, 3.0, 3.5, 4.0, 5.0 / 2.3	**D(Ø)** / **G/H** / **Post** 4.9 / 5.0 / 2.3	**D(Ø)** / **G/H** / **Post** 4.9 / 2.5, 3.0, 3.5, 4.0, 5.0 / 2.3	Same
Angled(˚)	17, 30	17	17, 30	Same
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Same

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Sterilization	Provided sterile (Radiation Sterile)	Sterile by end users	Sterile by end users	Different
Shelf-life	8 years	N/A	N/A	Different
Surface Treatment	N/A	N/A	N/A	Same
S.E.	**Similarities** Proposed Multi Angled Abutment has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate Multi Angled Abutment, K221684 and K182091. **Differences** The only difference is sterilization process. The proposed device is sterilized compared to the primary predicate; but it has same raw material, design, manufacturing process, etc. as that of the primary predicate. ∴ Proposed Multi Angled Abutment and the primary predicate are exactly same except sterilization process; therefore, the proposed device is substantially equivalent to the primary predicate.			

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5) Convertible Abutment

<table>
<tr><th></th><th>Subject Device</th><th>Reference Device</th><th>Remark</th></tr>
<tr><td>Device Name</td><td>Convertible Abutment</td><td>Convertible Abutment</td><td>Same</td></tr>
<tr><td>510(k) Number</td><td>-</td><td>K120847</td><td>-</td></tr>
<tr><td>Manufacturer</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Same</td></tr>
<tr><td>Design</td><td>  </td><td>  </td><td>Same</td></tr>
<tr><td>Indication for Use</td><td>The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>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.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>Use for cereating bridge case prosthesis with dislocated path.</td><td>Use for cereating bridge case prosthesis with dislocated path.</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0</td><td>1.0</td></tr>
<tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>1.2</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>1.2</td></tr>
</table>
</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4.0</td><td>1.0, 2.0, 3.0, 4.0</td><td>1.0</td></tr>
<tr><td>4.8</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>1.2</td></tr>
<tr><td>6.0</td><td>1.0, 2.0, 3.0, 4.0, 5.0</td><td>1.2</td></tr>
</table>
</td><td>Same</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td><td>Ti-6Al-4V (ASTM F136)</td><td>Same</td></tr>
<tr><td>Sterilization</td><td>Provided sterile (Radiation Sterile)</td><td>Sterile by end users</td><td>Different</td></tr>
<tr><td>Shelf-life</td><td>8 years</td><td>N/A</td><td>Different</td></tr>
<tr><td>Surface Treatment</td><td>N/A</td><td>N/A</td><td>Same</td></tr>
<tr><td>S.E.</td><td colspan="3">Similarities
Proposed Convertible Abutment has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device Convertible Abutment, K120847.</td></tr>
</table>

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	Differences The only difference is sterilization process. The proposed device is sterilized compared to the reference device; but it has same raw material, design, manufacturing process, etc. as that of the reference device. ∴ Proposed Converitble Abutment and the reference device are exactly same except sterilization process; therefore, the proposed device is substantially equivalent to the reference device.

6) Port Abutment

	Subject Device	**Primary Predicate**	**Remark**
Device Name	Port Abutment	Port Abutment	Same
510(k) Number	-	K182091	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Same
Indication for Use	The 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 intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Same
Principle of Operation	Using making implant retained overdenture at maxilla/mandible.	Using making implant retained overdenture at maxilla/mandible.	Same
Dimension (mm)	**D(Ø)** / **G/H** / **Post** 3.7 / 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 / 1.5	**D(Ø)** / **G/H** / **Post** 3.7 / 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 / 1.5	Same
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Same
Sterilization	Provided sterile (Radiation Sterile)	Sterile by end users	Different
Shelf-life	8 years	N/A	Different
Surface Treatment	N/A	N/A	Same
S.E.	**Similarities** Proposed Port Abutment has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate Port Abutment, K182091.		

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	Differences The only difference is sterilization process. The proposed device is sterilized compared to the primary predicate; but it has same raw material, design, manufacturing process, etc. as that of the primary predicate. ∴ Proposed Port Abutment and the primary predicate are exactly same except sterilization process; therefore, the proposed device is substantially equivalent to the primary predicate.

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7) Stud Abutment

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate</th><th>Reference Device</th><th>Remark</th></tr>
<tr><td>Device Name</td><td>Stud Abutment</td><td>Stud Abutment</td><td>Stud Abutment</td><td>Same</td></tr>
<tr><td>510(k) Number</td><td>-</td><td>K182091</td><td>K161689</td><td>-</td></tr>
<tr><td>Manufacturer</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Osstem Implant Co., Ltd</td><td>Same</td></tr>
<tr><td>Design</td><td>  </td><td>  </td><td>  </td><td>Same</td></tr>
<tr><td>Indication for Use</td><td>The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>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.</td><td>Same</td></tr>
<tr><td>Principle of Operation</td><td>Using making stud type overdenture prosthetics</td><td>Using making stud type overdenture prosthetics</td><td>Using making stud type overdenture prosthetics</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>3.5</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0</td><td>2.5, 3.35</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>3.5</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0</td><td>2.5</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr><tr><td>3.5</td><td>1.0, 2.0, 3.0, 4.0, 5.0, 6.0</td><td>3.35</td></tr></table></td><td>Same</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V (ASTM F136)</td><td>Ti-6Al-4V (ASTM F136)</td><td>Ti-6Al-4V (ASTM F136)</td><td>Same</td></tr>
<tr><td>Sterilization</td><td>Provided sterile (Radiation Sterile)</td><td>Sterile by end users</td><td>Sterile by end users</td><td>Different</td></tr>
</table>

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Shelf-life	8 years	N/A	N/A	Different
Surface Treatment	N/A	N/A	N/A	Same
S.E.	**Similarities** Proposed Stud Abutment has same design, function, dimension range and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the primary predicate and reference device Stud Abutment, K182091 and K161689. **Differences** The only difference is sterilization process. The proposed device is sterilized compared to the primary predicate; but it has same raw material, design, manufacturing process, etc. as that of the primary predicate. ∴ Proposed Stud Abutment and the primary predicate are exactly same except sterilization process; therefore, the proposed device is substantially equivalent to the primary predicate.			

8) Healing Abutment

	Subject Device	**Reference Device**	**Reference Device**	**Remark**
Device Name	Healing Abutment	Healing Abutment	Healing Abutment	Same
510(k) Number	-	K161604	K163634	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Southern Implants (Pty) Ltd.	Same
Design			N/A	Same
Indication for Use	The OSSTEM Abutment system is	The Osstem Implant System is indicated	Southern Implants' External Hex	Same

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<table>
<tr><td></td><td>intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td><td>for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Fixture System is intended to be used in the molar region.
Products with diameter of less than 3.25mm should be used exclusively for the laterl incisor in the maxilla and a central or lateral incisor in the mandible.</td><td>Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.</td><td></td></tr>
<tr><td>Principle of Operation</td><td>Used to make a natural soft tissue shape until setting up prosthetics. It is intended use to combine with implanted implant after osseointegration then removing cover screw.</td><td>Used to make a natural soft tissue shape until setting up prosthetics. It is intended use to combine with implanted implant after osseointegration then removing cover screw.</td><td>N/A</td><td>Same</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><th>D(Ø)</th><th>L</th></tr><tr><td>4.3</td><td>2.0, 6.0, 8.0</td></tr><tr><td>4.8</td><td>6.0, 8.0, 10.0</td></tr><tr><td>5.3</td><td>6.0, 8.0, 10.0, 11.0, 12.0</td></tr><tr><td>6.3</td><td>6.0, 8.0</td></tr><tr><td>7.3</td><td>6.0, 8.0</td></tr><tr><td>8.3</td><td>6.0, 8.0</td></tr><tr><td>9.3</td><td>5.0, 6.0, 8.0</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>L</th></tr><tr><td>4.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr><tr><td>4.8</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr><tr><td>5.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr><tr><td>6.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr><tr><td>7.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr><tr><td>8.3</td><td>5.0</td></tr></table></td><td><table><tr><th>D(Ø)</th><th>L</th></tr><tr><td>4.5</td><td>2.2, 3.0, 4.0, 5.0, 6.0, 8.0</td></tr><tr><td>5.5</td><td>2.2, 3.0, 4.0, 5.0, 6.0, 8.0, 12.0</td></tr><tr><td>6.5</td><td>2.2, 3.0, 4.0, 5.0, 6.0, 8.0, 12.0</td></tr><tr><td>7.5</td><td>2.2, 3.0, 4.0, 5.0, 6.0, 8.0, 12.0</td></tr></table></td><td>Different</td></tr>
<tr><td>Material</td><td>Titanium Gr.4 (ASTM F67)</td><td>Titanium Gr.4 (ASTM F67)</td><td>CPTi, Titanium alloy, Gold, CoCr</td><td>Same</td></tr>
<tr><td>Sterilization</td><td>Provided sterile
(Radiation Sterile)</td><td>Provided sterile
(Radiation Sterile)</td><td>N/A</td><td>Same</td></tr>
<tr><td>Shelf-life</td><td>8 years</td><td>8 years</td><td>N/A</td><td>Same</td></tr>
</table>

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Surface Treatment	Mini Connection: Anodizing Regular Connection : N/A	Mini Connection: Anodizing Regular Connection : N/A	N/A	Same
S.E.	**Similarities** Proposed Healing Abutment has same design, function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the reference device Healing Abutment, K161604. **Differences** The added diameter and length differ from the dimension range of the reference device. However, since Healing Abutment is used temporarily to make natural soft tissue shape until setting up prosthetics, it does not required any performance. In addition, proposed lengths are within in dimension range of reference device, already cleared in K163634. Therefore, we don't consider additional performance testing. ∴ Proposed Healing Abutment and the reference device have common in design, function, indication for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed device is substantially equivalent to the reference device.			

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Summary of Non-clinical Performance Testing

Non-clinical testing data were referenced by prior clearances to demonstrate substantial equivalence.

Biocompatibility Evaluation
Biocompatibility testing was considered followed 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,"* The TS Abutment System has same materials, manufacturer, manufacturing process, surface treatment etc., as primary predicate and reference devices. Therefore, we didn't conduct additional biocompatibility test.

Sterilization Validation and Shelf-life
Validation of the gamma irradiation process was previously conducted for the predicated device. The processes of prediates since the clearance and the change in dimensions of the subject devices do not create the new worst case scenario or sterilization; therefore, additional validation is not required. In addition, TS Abutment System are made with titanium and titanium alloy we don't consider about shelf life of material by itself because this metal is widely known that it generally has no adversely affect by aging. Therefore we certify that product such like metal has no shelf life.

Pyrogen Test
Bacterial Endotoxin Test Report on implants according to ISO 10993-11:2006 and USP<151> referenced in K161604.

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. Processes of predicates since the clearance and the change in dimensions of the subject device do not create the new worst case scenario or bench testing.

MR Compatibility
Non-clinical worst-case MRI review was performed to evaluate the Subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

7. Summary of Clinical Testing

No clinical studies are submitted.

8. 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 TS Abutment System is substantially equivalent to the predicated devices as herein.