Zeros Co., Ltd.
Uk Joo
CTO
138-13, Pyeonggang-ro 345beon-gil
Gangseo-gu, Busan 46700
REPUBLIC OF KOREA

March 25, 2024

Re: K232268
Trade/Device Name: STERI-OSS Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 20, 2024
Received: February 20, 2024

Dear Uk Joo:

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)*
K232268

Device Name
STERI-OSS Implant System

Indications for Use *(Describe)*
STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.

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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510(k) Summary

Date revised : March 24, 2024

I. SUBMITTER

Zeros Co., Ltd.
138-13, Pyeonggang-ro 345beon-gil, Gangseo-gu, Busan, 46700, Rep, of Korea
TEL: +82-51-831-0094
FAX: +82-51-831-0095
Contact Name: Uk Hyon Joo
Email: ecometal@nate.com

II. DEVICE INFORMATION

- Device's Trade name: STERI-OSS Implant System
- Classification Name: Implant, Endosseous, Root-Form
- Device's Common Name: Endosseous Dental Implant
- Regulation Number 872.3640
- Class: 2
- Primary Product Code: DZE
- Secondary Product Code: NHA

III. PREDICATE DEVICE

Primary Predicate Device:

- K121995, TS Fixture System, OSSTEM Implant Co., Ltd.

Reference Device:

- K120503, CMI Implant IS II Active, Neobiotech Co., Ltd.
- K202039, Honorst Implant System, MEDIMECCA Co., Ltd.
- K182091, Osstem Abutment System, Osstem Implant Co., Ltd.
- K161689, OSSTEM Implant System – Abutment, Osstem Implant Co., Ltd.
- K172100, URIS OMNI System, TruAbutment Korea Co., Ltd.
- K210354, SNUCONE Bone Level Implant System, SNUCONE Co., Ltd.
- K052823, Implantium Abutment, Dentium Inc.
- K140934, HIOSSEN Implant System, HiOSSEN Inc.
- K161604, OSSTEM Implant System, Osstem Implant Co., Ltd.

IV. DEVICE DESCRIPTION

STERI-OSS Implant System, Fixture is a medical device made of titanium that is inserted into the maxillary or mandibular alveolar bone to support prosthesis such as artificial teeth for the patient's recovery of masticatory function.

STERI-OSS Implant System, Abutment is inserted to support prosthesis such as artificial teeth, and is a medical device made of titanium alloy. It connects artificial teeth with a fixture implanted in the maxillary or mandibular alveolar bone where teeth are lost.

V. INDICATION FOR USE

STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.

VI. COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE REDICATE DEVICE

Table 1 : Substantial Equivalence – Indication for Use Statements

Item	Subject Device	Primary Predicate Device	Reference Device	Reference Device
510(k) Number	K232268	K121995	K120503	K202039
Device Name	STERI-OSS Implant System	TS Fixture System	CMI Implant IS II Active	Honorst Implant System
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	Neobiotech Co., Ltd.	MEDIMECCA Co., Ltd.
Indications for Use Statement	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading	The TS Fixture System is designed for dental implant surgery; it is placed in the maxillary or mandibular alveolar bone through a surgical procedure, and after osseointegration with the alveolar bone, it can replace a lost tooth by connecting the abutment post. The TS Fixture System & TSIII SA Ultra-Wide Fixture are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The CMI Implant IS II active is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Honorst Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Honorst Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading
Substantial Equivalence Discussion	**Similarity :** The subject device, "STERI-OSS Implant System", and primary predicate device, 'TS Fixture System' (K121995) and reference devices 'CMI Implant IS II Active' (K120503)', 'Hornorst Implant System' (K202039) are dental implants that can recover masticatory function when teeth are lost.			

	Difference : Indication for use of subject device is slight differences in phrase with the primary predicate device (K121995), reference device (K120503), but fundamental indication is same. Therefore, Indication for Use statement of the subject device, "STERI-OSS Implant System" is identical and substantially equivalent to the identified primary predicate device, K121995 and reference devices, K202039.

Table 2 : Substantial Equivalence - EQUIVALENCE DISCUSSION

1. Fixture

<table>
<tr><th>Item</th><th>Subject Device</th><th>Primary Predicate Device</th><th>Reference Device</th><th>Reference Device</th></tr>
<tr><td>510(k) Number</td><td>K2322685</td><td>K121995</td><td>K120503</td><td>K202039</td></tr>
<tr><td>Device Name</td><td>STERI-OSS Implant System</td><td>TS Fixture System</td><td>CMI Implant IS II Active</td><td>Honorst Implant System</td></tr>
<tr><td>Manufacturer</td><td>Zeros Co., Ltd.</td><td>Osstem Implant Co., Ltd.</td><td>Neobiotech Co., Ltd.</td><td>MEDIMECCA Co., Ltd.</td></tr>
<tr><td>Design</td><td>  </td><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Connection type</td><td>Internal Hex</td><td>Internal Hex</td><td>Internal Hex</td><td>Internal Hex</td></tr>
<tr><td>Material</td><td>Pure Titanium Grade 4 (ASTM F67)</td><td>Pure Titanium Grade 4 (ASTM F67)</td><td>Pure Titanium Grade 4 (ASTM F67)</td><td>Pure Titanium Grade 4 (ASTM F67)</td></tr>
<tr><td>Diameter & Length</td><td>
<table>
<tr><th>Diameter (mm)</th><th>Length(mm)</th></tr>
<tr><td>3.8</td><td>8.5, 9, 10, 11, 11.5, 12, 13, 15</td></tr>
<tr><td>4.2</td><td>7, 8, 8.5, 9, 10, 11, 11.5, 12, 13, 15</td></tr>
<tr><td>4.6</td><td>7, 8, 8.5, 9, 10, 11, 11.5, 12, 13, 15</td></tr>
<tr><td>5.1</td><td>7, 8, 8.5, 9, 10, 11, 11.5, 12, 13</td></tr>
<tr><td>5.5</td><td>7, 8, 8.5, 9, 10, 11, 11.5, 12, 13</td></tr>
<tr><td>6.0</td><td>7, 8, 8.5, 9, 10, 11, 11.5, 12</td></tr>
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<u>TSII SA Fixture</u>
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<tr><th>Diameter (mm)</th><th>Length(mm)</th></tr>
<tr><td>3.5</td><td>8.5, 10, 11.5, 13, 15</td></tr>
<tr><td>4.2</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr>
<tr><td>4.4</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr>
<tr><td>4.9</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr>
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<u>TSIII SA Fixture</u>
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<tr><th>Diameter (mm)</th><th>Length(mm)</th></tr>
<tr><td>3.75</td><td>10, 11.5, 13, 15</td></tr>
<tr><td>3.77</td><td>8.5</td></tr>
<tr><td>4.2</td><td>10, 11.5, 13, 15</td></tr>
<tr><td>4.25</td><td>7, 8.5</td></tr>
<tr><td>4.6</td><td>10, 11.5, 13, 15</td></tr>
<tr><td>4.63</td><td>8.5</td></tr>
<tr><td>4.65</td><td>7</td></tr>
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<table>
<tr><th>Diameter (mm)</th><th>Length(mm)</th></tr>
<tr><td>4.5</td><td>7.3, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>5</td><td>7.3, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>5.5</td><td>7.3, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr>
<tr><td>6</td><td>7.3, 8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>7</td><td>7.3, 8.5, 10.0, 11.5, 13.0</td></tr>
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<table>
<tr><th>Diameter (mm)</th><th>Length(mm)</th></tr>
<tr><td>3.75</td><td>8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>4.2</td><td>7.0, 8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>4.6</td><td>7.0, 8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>5.1</td><td>7.0, 8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>5.5</td><td>7.0, 8.5, 10.0, 11.5, 13.0</td></tr>
<tr><td>6</td><td>7.0, 8.5, 10.0, 11.5, 12.5</td></tr>
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<tr><td>5.08</td><td>8.5</td></tr>
<tr><td>5.1</td><td>7</td></tr>
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<u>TSIII SA Ultra-Wide Fixture</u>
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<tr><th>Diameter (mm)</th><th>Length(mm)</th></tr>
<tr><td>5.92</td><td>11.2</td></tr>
<tr><td>5.95</td><td>9.7</td></tr>
<tr><td>6</td><td>7.2, 8.2</td></tr>
<tr><td>6.8</td><td>7.2, 8.2, 9.7, 11.2</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>Surface Treatment</td><td>SLA</td><td>SLA</td><td>SLA</td><td>SLA</td></tr>
<tr><td>Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td><td>Gamma Sterilization</td></tr>
<tr><td>Shelf life</td><td>5 years</td><td>8 years</td><td>5 years</td><td>5 years</td></tr>
<tr><td>Substantial Equivalence Discussion</td><td colspan="4"><u>Similarity :</u>
The subject device, "STERI-OSS Implant System" has almost the same indications for use, raw material, and design when compared to the primary predicate device, 'TS Fixture System'(K121995). The fixture surface treatment method is the same as SLA, and the product is sterilized by gamma irradiation.

In addition, the subject device is the same as the reference devices 'CMI Implant IS II Active'(K120503) and 'Hornorst Implant System'(K202039) in the raw material, design, surface treatment method (SLA), and sterilization method (gamma irradiation).

<u>Difference :</u>
In addition, although there is a slight difference between the dimensions of the subject device and that of the predicate device (K121995) and reference devices (K120503, K202039), it is judged that they exist within a similar dimensional range overall.

Therefore, "STERI-OSS Implant System" is similar in that they are threaded, root form implants with SLA surface treated. The subject and predicate fixtures are a similar body shape design such as cylindrical body design, similar dimension range. The difference is very minor not affecting substantial equivalence.</td></tr>
</table>

2. Abutment

Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K182091	K172100
Device Name	STERI-OSS Implant System	Osstem Abutment System	URIS OMNI System
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	TruAbutment Korea Co., Ltd.

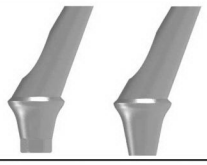
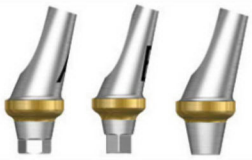
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	URIS OMNI 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.
Part Name	Straight Abutment	Transfer Abutment	D Basis Abutment-Cemented Type
Design			
Principle of operation	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	4.0, 4.6, 5.0, 6.0, 7.0	4.0, 4.5, 5.5, 6.5
Post Height(mm)	4.0, 5.5, 7.0	4.0, 5.5. 7.0	4.0, 5.5, 7.0
Gingival Height(mm)	1.0, 2.0, 3.0, 4.0, 5.0, 6.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
Surface Treatment	None	TiN Coated (partially)	None
Substantial Equivalence Discussion	**Similarity :** - Subject device, "Straight Abutment" is generally used for cement-retained restoration, and has the same function, indications for use, material compared to that of the reference device, 'Transfer Abutment' in Osstem Abutment System (K182091). Also, subject device has the similar design (dimension range) and appearance compared to that of the reference device (K182091). - Indication for use of subject device is slight differences in phrase with the reference device (K182091), but fundamental indication is same. - Subject device has the same function, indications for use, material, surface treatment compared to that of the reference device (K172100). **Difference :** The subject device, "Straight Abutment", has a machined surface without surface treatment and is similar to the reference device (K172100). The reference device		

	(K182091) was partially coated with TiN. Therefore, the subject device, "Straight Abutment" is very similar to the reference device (K182091) in terms of function, purpose of use, raw materials (Ti alloys), design, etc., except for the different surface treatment. The difference is minor not affecting substantial equivalence.

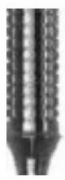
Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K161689	K172100
Device Name	STERI-OSS Implant System	OSSTEM Implant System - Abutment	URIS OMNI System
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	TruAbutment Korea Co., Ltd.
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	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.	URIS OMNI 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.
Part Name	Solid Abutment	Rigid Abutment	D Basis Abutment - Direct Type
Design			
Principle of operation	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	4.0, 4.6, 5.0, 6.0, 7.0	4.0, 4.5, 5.5, 6.5
Post Height(mm)	4.0, 5.5, 7.0	4.0, 5.5. 7.0	4.0, 5.5, 7.0

Gingival Height(mm)	1.0, 2.0, 3.0, 4.0, 5.0, 6.0	1.0, 2.0, 3.0, 4.0, 5.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
Surface Treatment	None	TiN Coated (partially)	None
Substantial Equivalence Discussion	**Similarity :** - Subject device, "Solid Abutment" is generally used for cement-retained restoration, and has the same function, indications for use, material compared to that of the reference device, 'Rigid Abutment' in Osstem Abutment System (K161689). Also, subject device has the similar design (dimension range) and appearance compared to that of the reference device (K161689). - Indication for use of subject device is slight differences in phrase with reference device (K161689), but fundamental indication is same. - Subject device has the same function, indications for use, material, surface treatment compared to that of the reference device (K172100). **Difference :** The subject device, "Solid Abutment", has a machined surface without surface treatment and is similar to the reference device (K172100). The reference device (K161689) was partially coated with TiN. Therefore, the subject device and reference devices (K161689, K172100) have the similar intended use, design including diameter and lengths, and are made of same materials (Ti alloys) except for the different surface treatment. The difference is minor not affecting substantial equivalence.		

Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K182091	K210354
Device Name	STERI-OSS Implant System	OSSTEM Implant System - Abutment	SNUCONE Bone Level Implant System
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	SNUCONE Co., LTD.
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system	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.	SNUCONE Bone Level 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 terminal or intermediate Abutment support for fixed bridge work. SNUCONE Bone Level Implant System is dedicated for two stage

	is intended for delayed loading.		surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.
Part Name	Angled Abutment	Angled Abutment	Abiding Couple Angled Abutment
Design			
Principle of operation	Cement retained restoration	Cement retained restoration	Cement or screw retained restoration
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	4.0, 4.5, 5.0, 6.0	4.0, 4.5, 5.0, 5.5, 6.5
Post Height(mm)	8.0	8.0	7.0
Gingival Height(mm)	1.0, 2.0, 3.0, 4.0, 5.0, 6.0	2.0, 4.0	2.0, 4.0, 6.0
Angle	15°, 25°	17°	15°, 25°
Surface Treatment	None	TiN Coated (partially)	None / Anodized
Substantial Equivalence Discussion	**Similarity :** - Subject device, "Angled Abutment" is generally used for cement-retained restoration, and has the same function, indications for use, material compared to that of the reference device, 'Angled Abutment' in Osstem Abutment System (K182091). Also, subject device has the similar design and appearance compared to that of the reference device (K182091). - Subject device, "Angled Abutment" has the same function, indications for use, material, and the similar design (dimension range) and appearance compared to that of the reference device (K210354). - Indication for use of subject device is slight differences in phrase with reference devices, but fundamental indication is same. **Difference :** - In terms of surface treatment, the subject device, "Angled Abutment" has a machined surface without surface treatment and is similar to the product without surface treatment among the reference devices (K210354). The reference device (K182091) was partially coated with TiN. - Dimension difference : Compared to the reference device (K182091), models with diameters of 5.5, 6.5 mm, and gingival heights of 1.0, 3.0, 5.0, and 6.0 mm are added to the subjective device. Also, there are differences in angles of 15°, 25° in subjective device and 17° in reference device (K182091). The dimensional		

	differences were addressed by the provided mechanical bench testing. Therefore, the subject device, "Angled Abutment" is similar to the reference (K182091) in terms of function, purpose of use, raw materials (Ti alloys), design (dimension range and appearance) etc., except for the different surface treatment. The difference is minor not affecting substantial equivalence.

Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K161689	K052823
Device Name	STERI-OSS Implant System	OSSTEM Implant System - Abutment	Implantium Abutment
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	Dentium Inc.
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	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 Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.
Part Name	Temporary Abutment	Temporary Abutment	Temporary Abutment
Design			
Principle of operation	temporary prostheses / Cement/screw retained restoration	temporary prostheses / Cement/screw retained restoration	temporary prostheses / Cement/screw retained restoration
Material	Ti6Al4V ELI (ASTM F136)	Titanium Gr.3 (ASTM F67)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	4.5	4.0, 4.5	4.5
Post Height(mm)	10.0 (minimum post height of	10.0	10.0

	4 mm for single-unit restorations)		
Gingival Height(mm)	1.0	1.0, 3.0	1.0
Surface Treatment	None	None	None
Maximum duration	Less than 180 days	Less than 180 days	Less than 180 days
Substantial Equivalence Discussion	**Similarity :** - Subject device, "Temporary Abutment" is generally used for cement/screw-retained restoration, and temporary prosthesis to maintain aesthetic appearance until final prosthesis is made. - Subject device has the same function and the similar indications for use, dimension range compared to that of the reference device (K161689). - Subject device has the same function, indications for use, material, and the similar design compared to that of the reference device (K052823). - Indication for use of subject device is slight differences in phrase with the reference devices, but fundamental indication is same. **Difference :** - In terms of appearance (shape of the post), subjective device is different with that of the reference device (K161689). - In the case of raw materials, Ti alloy is used for the subjective device, and cp-Ti is used for the reference device (K161689). Therefore, the subject device, "Temporary Abutment" is similar to the reference device (K161689) in terms of function, purpose of use, dimension range, except for the different appearance and raw-materials. The difference is minor not affecting substantial equivalence.		

3. Screw

Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K161689	K052823
Device Name	STERI-OSS Implant System	Osstem Abutment System	Implantium abutments
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	Dentium Inc.
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment	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 Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically

	support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.		placed, the endosseous dental implant abutment device is attached to it.
Part Name	Abutment Screw	Abutment Screw	Abutment Screw
Design			
Principle of operation	To connect the abutment to the fixture	To connect the abutment to the fixture	To connect the abutment to the fixture
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	2.3	2.0, 2.05, 2.2, 2.3, 2.5	2.3
Length (mm)	9.3	3.35, 5.6, 7.5, 8.35, 9.6, 10.2	7.3, 10.2
Surface Treatment	None	None	None
Substantial Equivalence Discussion	**Similarity :** - Subject device, "Abutment Screw" is common in design to connect the abutment to the fixture, and has the same function, indications for use, material, design & appearance, surface treatment compared to that of the reference device (K161689) and reference device (K052823). - Indication for use of subject device is slight differences in phrase with the reference devices, but fundamental indication is same. **Difference :** - Dimension difference : There is a difference in diameter and length compared to the reference device (K161689). However, the subjective device's dimension is within the reference device dimensions. Therefore, the subject device, "Abutment Screw" is similar to the reference device (K161689) in terms of function, purpose of use, raw materials (Ti alloys), design (dimension range and appearance), and surface treatment. The difference of dimension is minor not affecting substantial equivalence.		

Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K140934	K052823
Device Name	STERI-OSS Implant System	HIOSSEN Implant System	Implantium abutments

Manufacturer	Zeros Co., Ltd.	HiOSSEN Inc.	Dentium Inc.
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	The HIOSSEN 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. ETIII SA Ultra Wide Fixture is intended to be used in the loar region.	The Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.
Part Name	Cover Screw	Cover Screw	Cover Screw
Design			
Principle of operation	To protect the internal portion of the implant	To protect the internal portion of the implant	To protect the internal portion of the implant
Material	Ti6Al4V ELI (ASTM F136)	Titanium Gr 4 (ASTM F67)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	3.5	3.03, 3.58, 3.25, 3.4, 3.75, 3.9	3.4, 3.6, 3.8
Length (mm)	5.5	5.25, 5.9, 6.25, 6.85, 6.9, 7.5	4.70 ~ 8.92
Surface Treatment	None	Anodized	None / Anodized
Substantial Equivalence Discussion	**Similarity :** - Subject device, “Cover Screw” is a common design, and has the same function, indications for use, design & appearance, compared to that of the reference device (K140934) and reference device (K052823). - Indication for use of subject device is slight differences in phrase with the reference devices, but fundamental indication is same. **Difference :** - The difference in raw materials is Ti alloy for subjective devices and cp-Ti for reference devices (K140934). But, for reference devices (K052823), raw material information is the same. - In subject device, one size is proposed, and cover screws of various sizes are proposed for reference devices (K140934). It exists in a range of dimensions compared to reference devices (K140934). - In terms of surface treatment, the subject device, “Cover Screw” and reference device (K052823) have none-surface treatment. In reference device (K140934),		

	surface treatment as anodized is applied to the product. Therefore, the subject device, "Cover Screw" is similar to the reference device (K140934) in terms of function, purpose of use, design (dimension range and appearance), except for the different surface treatment. The difference is minor not affecting substantial equivalence.

Item	Subject Device	Reference Device	Reference Device
510(k) Number	K232268	K161604	K052823
Device Name	STERI-OSS Implant System	Osstem Implant System	Implantium abutments
Manufacturer	Zeros Co., Ltd.	Osstem Implant Co., Ltd.	Dentium Inc.
Indication for use	STERI-OSS Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. STERI-OSS Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading	The OSSTEM 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 Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.
Part Name	Healing Abutment	Healing Abutment	Healing Abutment
Design			
Principle of operation	To help the soft tissue of gum naturally formed.	To help the soft tissue of gum naturally formed.	To help the soft tissue of gum naturally formed.
Material	Ti6Al4V ELI (ASTM F136)	Titanium Gr 4 (ASTM F67)	Ti6Al4V ELI (ASTM F136)

Diameter (mm)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	4.3, 4.8, 5.3, 6.3, 7.3, 8.3	4.04 ~ 9.64
Length (mm)	9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0	7.5, 8.5, 9.5, 10.5, 11.5, 12.5, 13.5, 14.5	8.70 ~ 14.66
Surface Treatment	None	Anodized	None
Substantial Equivalence Discussion	**Similarity :** - Subject device, "Healing Abutment" is a common design, and has the same function, indications for use, design & appearance compared to that of the reference device (K161604) and reference device (K052823). - Indication for use of subject device is slight differences in phrase with the reference devices, but fundamental indication is same. **Difference :** - The difference in raw materials is Ti alloy for subjective devices and cp-Ti for reference devices (K161604). But, for reference devices, raw material information is the same. - In subjective device and reference device (K052823), surface treatment was not applied. But surface treatment with anodizing was applied to reference device (K161604) partially. - In dimension, there is a slight difference between subjective and reference device (K161604). Therefore, the subject device, "Healing Abutment" is similar to the reference device (K161604) in terms of function, purpose of use, design (dimension range and appearance) etc.		

VII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device has same device characteristics and indications for use with the primary predicate and reference device as dental implant system. It is intended purpose as they are placed in the alveolar bone to replace the function of missing tooth.

The various dimensions of subject devices are slightly different from the predicate devices. However, the dimensions of the subject device are in the range of the dimensions of the predicate and reference devices.

Differences in dimensions are supported by the mechanical bench testing. The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics doesn't impact substantial equivalence.

Therefore, it is concluded that STERI-OSS Implant System is substantially equivalent to the predicate devices.

VIII. NON CLINICAL TESTING

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Surface modification testing, utilizing EDS and SEM evaluations was conducted to demonstrate consistency and appropriateness of the S.L.A. treated implant surface.
- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario

- Gamma sterilization validation Test Report according to ISO 11137-1 and ISO 11137-2
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, ISO 11138-1 and ISO 11138-3
- Shelf life Test according to ASTM F88, ASTM F1140, ASTM F1929, and ASTM F2096
- Biocompatibility evaluations according to ISO 10993-1 and Biocompatibility testing according to ISO 10993-5 and ISO 10993-12

Pyrogen and Endotoxin Test

The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL in accordance with the USP <85> "Bacterial Endotoxins Test".

MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the STERI-OSS Implant System in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, 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. No.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.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate devices.

IX. 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 Zeros Co., Ltd. concludes that the STERI-OSS Implant System is substantially equivalent to the predicate device as described herein.