August 19, 2026

Zeros Co., Ltd.
Uk-Hyon Joo
Bldg. A, 27, Seogimhaesandnan-Gil, Gimhae-Si
Gyeongsangnam-Do, 50967
REPUBLIC OF KOREA

Re: K260463
Trade/Device Name: ZEROS Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 23, 2026
Received: July 23, 2026

Dear Uk-Hyon 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260463

Device Name
ZEROS Dental Implant System

Indications for Use *(Describe)*
ZEROS Dental Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. ZEROS Dental 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date revised: August 19, 2026

I. SUBMITTER

Zeros Co., Ltd.
Building A, 27, Seogimhaesandnan-gil, Gimhae-si, Gyeongsangnam-do, 50967, Republic of Korea
TEL: +82-55-905-0094
FAX: +82-55-905-0095
Contact Name: Uk Hyon Joo
Email: ecometal@nate.com

II. DEVICE INFORMATION

- Device's Trade name: ZEROS Dental 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:

- K232268, STERI-OSS Implant System, Zeros Co., Ltd.

Reference Device:

- K120503, CMI Implant IS-II Active, Neobiotech Co., Ltd.
- K082213, GS III Fixture System, OSSTEM Implant Co., Ltd.

IV. DEVICE DESCRIPTION

ZEROS Dental 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.

ZEROS Dental 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.

This 510(k) submission is submitted to reflect the following changes to the ZEROS Dental Implant System:

- Manufacturing site change
- Trade name addition
- Model updates – addition of an M2 Fixture (new size configuration within the existing M2 Fixture line)
- Model line expansion – addition of the M3 Fixture line (a new fixture line)

The M3 Fixture differs from the M2 Fixture primarily in thread design: the M3 Fixture utilizes a triple-thread configuration, whereas the M2 Fixture retains the thread configuration of the primary predicate device (K232268). Other technological characteristics of the M3 Fixture are identical to those of the M2 Fixture and the primary predicate device.

V. INDICATION FOR USE

ZEROS Dental Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. ZEROS Dental 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

The ZEROS Dental Implant System includes one additional model in the M2 Fixture group and a new M3 Fixture model, both marketed under an additional trade name. Other components, including abutments and screws, are unchanged and therefore not included in this comparison. This section provides a comparison between the subject device and the predicate device and reference devices for all technological characteristics, intended use, and safety considerations applicable to the predicate device size combinations.

Table 1 : Substantial Equivalence – Indication for Use Statements

Item	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2
510(k) Number	K260463	K232268	K120503	K082213
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System	CMI Implant IS-II Active	GS III Fixture System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.	Neobiotech Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use Statement	ZEROS Dental 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. ZEROS Dental Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	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 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.	The GS III Fixture 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 bridgework. The GS III Fixture system is for single and tow stage surgical procedures. It is not for immediate load.
Substantial	The indication for use statement is consistent with the subject device with respect to patient population, restoration types, and surgical			

Equivalence Discussion	approach. Reference Device 1 is indicated for immediate loading, whereas the subject device is indicated for delayed loading only. Delayed loading represents a more conservative loading condition and therefore does not raise different questions of safety or effectiveness for the subject device's intended use of restoring chewing function.

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 1</th><th>Reference Device 2</th></tr>
<tr><td>510(k) Number</td><td>K260463</td><td>K232268</td><td>K120503</td><td>K082213</td></tr>
<tr><td>Device Name</td><td>ZEROS Dental Implant System</td><td>STERI-OSS Implant System</td><td>CMI Implant IS-II Active</td><td>GS III Fixture System</td></tr>
<tr><td>Manufacturer</td><td>Zeros Co., Ltd.</td><td>Zeros Co., Ltd.</td><td>Neobiotech Co., Ltd.</td><td>Osstem Implant 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>Surface Treatment</td><td>SLA</td><td>SLA</td><td>S.L.A</td><td>RBM</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>5 years</td><td>-</td><td>8 years</td></tr>
<tr><td>Diameter & Length</td><td><u>M2 Fixture</u>
<table><tr><th>Diameter (mm)</th><th>Length(mm)</th></tr><tr><td>3.8</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>4.6</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr><tr><td>5.1</td><td>7, 8.5, 10, 11.5, 13</td></tr><tr><td>5.5</td><td>7, 8.5, 10, 11.5, 13</td></tr><tr><td>6.0</td><td>7, 8.5, 10, 11.5, 13</td></tr></table></td><td><u>M2 Fixture</u>
<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></table></td><td><u>CMI Implant IS-II Active</u>
<table><tr><th>Diameter (mm)</th><th>Length(mm)</th></tr><tr><td>3.5</td><td>7.3, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr><tr><td>4.0</td><td>7.3, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr><tr><td>4.5</td><td>7.3, 8.5, 10.0, 11.5, 13.0, 15.0</td></tr></table></td><td><u>GS III Fixture</u>
<table><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>4.0</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr><tr><td>4.5</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr><tr><td>5.0</td><td>7, 8.5, 10, 11.5, 13, 15</td></tr></table></td></tr>
</table>

M3 Fixture

Diameter (mm)	Length(mm)
3.8	8.5, 10, 11.5, 13, 14.5, 15
4.2	7, 8.5, 10, 11.5, 13, 14.5, 15
4.6	7, 8.5, 10, 11.5, 13, 14.5, 15
5.1	7, 8.5, 10, 11.5, 13
5.5	7, 8.5, 10, 11.5, 13
6.0	7, 8.5, 10, 11.5, 13
5.1	7, 8, 8.5, 9, 10, 11, 11.5, 12, 13
5.5	7, 8, 8.5, 9, 10, 11, 11.5, 12, 13
6.0	7, 8, 8.5, 9, 10, 11, 11.5, 12
5.0	7.3, 8.5, 10.0, 11.5, 13.0, 15.0
5.5	7.3, 8.5, 10.0, 11.5, 13.0, 15.0
6.0	7.3, 8.5, 10.0, 11.5, 13.0, 15.0
7.0	7.0, 7.3, 8.5, 10.0, 11.5, 13.0
8.0	7.0, 7.3, 8.5, 10.0, 11.5, 13.0

2. Abutment

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	Straight Abutment	Straight Abutment
Design		
Principle of operation	Cement retained restoration	Cement retained restoration
Material	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, 5.5, 6.0, 6.5
Post Height(mm)	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
Surface Treatment	None	None
Substantial Equivalence Discussion	The subject device, “Straight Abutment”, is equivalent with the primary predicate device (K232268).	

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	Solid Abutment	Solid Abutment
Design		
Principle of operation	Cement retained restoration	Cement retained restoration
Material	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, 5.5, 6.0, 6.5
Post Height(mm)	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
Surface Treatment	None	None
Substantial Equivalence Discussion	The subject device, “Solid Abutment”, is equivalent with the primary predicate device (K232268).	

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	Angled Abutment	Angled Abutment
Design		
Principle of operation	Cement retained restoration	Cement retained restoration
Material	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, 5.5, 6.0, 6.5
Post Height(mm)	8.0	8.0
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
Angle	15°, 25°	15°, 25°
Surface Treatment	None	None
Substantial Equivalence Discussion	The subject device, “Angled Abutment”, is equivalent with the primary predicate device (K232268).	

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	Temporary Abutment	Temporary Abutment
Design		
Principle of operation	temporary prostheses / Cement/screw retained restoration	temporary prostheses / Cement/screw retained restoration
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	4.5	4.5
Post Height(mm)	10.0 (minimum post height of 4 mm for single-unit restorations)	10.0 (minimum post height of 4 mm for single-unit restorations)
Gingival Height(mm)	1.0	1.0
Surface Treatment	None	None
Maximum duration	Less than 180 days	Less than 180 days
Substantial Equivalence Discussion	The subject device, “Temporary Abutment”, is equivalent with the primary predicate device (K232268).	

3. Screw

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	Abutment Screw	Abutment Screw
Design		
Principle of operation	To connect the abutment to the fixture	To connect the abutment to the fixture
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	2.3	2.3
Length (mm)	9.3	9.3
Surface Treatment	None	None
Substantial Equivalence Discussion	The subject device, “Abutment Screw”, is equivalent with the primary predicate device (K232268).	

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	Cover Screw	Cover Screw
Design		
Principle of operation	To protect the internal portion of the implant	To protect the internal portion of the implant
Material	Ti6Al4V ELI (ASTM F136)	Ti6Al4V ELI (ASTM F136)
Diameter (mm)	3.5	3.5
Length (mm)	5.5	5.5
Surface Treatment	None	None
Substantial Equivalence Discussion	The subject device, “Cover Screw”, is equivalent with the primary predicate device (K232268).	

Item	Subject Device	Primary Predicate Device
510(k) Number	K260463	K232268
Device Name	ZEROS Dental Implant System	STERI-OSS Implant System
Manufacturer	Zeros Co., Ltd.	Zeros Co., Ltd.
Part Name	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.
Material	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, 5.5, 6.0, 6.5
Length (mm)	9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0	9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0
Surface Treatment	None	None
Substantial Equivalence Discussion	The subject device, “Healing Abutment”, is equivalent with the primary predicate device (K232268).	

VII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The ZEROS Dental Implant System fixtures share the identical material, surface treatment (SLA), sterilization method, connection type (Internal Hex), and intended use as the primary predicate device (K232268). Certain M2 Fixture sizes previously cleared under K232268 were removed for portfolio optimization, and a new Ø6.0 x 13mm configuration was added under the M2 Fixture line, and M3 Fixture line was added, supported by Reference Device 1 (K120503) and bounding ISO 14801 fatigue data. Reference Device 2 (K082213) was included primarily for its micro/triple-thread design, similar to the new M3 Fixture, and shares the same classification and material as the subject device.

VIII. NON CLINICAL TESTING

The subject device is similar to the predicate devices, therefore it demonstrates substantial equivalence to the predicate devices according to the following standards.

- Biocompatibility evaluations according to ISO 10993-1 and Biocompatibility testing according to ISO 10993-5 and ISO 10993-12

Testing Referenced Under K232268

- 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

Testing Referenced Under K232268

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 "Bacterial Endotoxins Test".

Testing Referenced Under K232268

MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the ZEROS Dental Implant System in the MRI environment using scientific rationale

and published literature (e.g., Terry 0. 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.

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 ZEROS Dental Implant System is substantially equivalent to the predicate device as described herein.