Osstem Implant CO., LTD.
% Peter Lee
RA/QA Manager
HioSSEN Inc.
85 Ben Fariless Dr.
Fariless Hills, Pennsylvania 19030

9/23/23

Re: K222778
Trade/Device Name: Osstem Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 3, 2023
Received: August 9, 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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

Sherrill Lathrop Blitzer

for Andrew 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)*

K222778

Device Name
OSSTEM Implant System

Indications for Use *(Describe)*

The Osstem Implant System is indicated 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 Implant System is intended to be used in the molar region.

Products with diameter of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.

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: September 23, 2023

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	:	Osstem Implant System
- Classification Name	:	Endosseous dental implant
- Regulation Number	:	21CFR872.3640
- Devce Classification	:	Class II
- Classification Product Code	:	DZE
- Subsequent Product Code	:	NHA

3. Predicate Device

Primary Predicate	
K161604	OSSTEM Implant System
Reference Device	
K121995	TS Fixture System
K163557	SS SA Fixture
K163634	External Hex Implants

4. Indication for use

The Osstem Implant System is indicated 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 Implant System is intended to be used in the molar region.
Products with diameter of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.

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5. Device Description

The Osstem Implant System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. The Ultra-Wide implants are intended to be used only to replace molar teeth and angled abutments are not to be used with the Ultra-Wide implants.
Osstem Implant System is similar to other commercially available products based on the intended use, technology used, claims, material composition employed and performance characteristics.

The specifications of the proposed device are as follow;

Device	Content	
TSIII SA Implant	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.
	Material	Titanium Grade 4 (ASTM F67)
	Surface	SA surface treatment
	Diameter (D) and Length (L)	ø3.75 x L 18, 20 mm ø3.77 x L 7 mm ø4.25 x L 7 mm ø4.65 x L 7 mm ø5.45 x L 10, 11.5, 13, 15 mm ø5.48 x L 8.5 mm ø5.5 x L 7mm
TSIII SA Implant (Non-Hex) Ø3.2	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.
	Material	Titanium Alloy (ASTM F136)
	Surface	SA surface treatment
	Diameter (D) and Length (L)	ø3.2 x L 8.5, 10, 11.5, 13, 15 mm
TSIII SA Implant (Non-Hex)	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.
	Material	Titanium Grade 4 (ASTM F67)
	Surface	SA surface treatment
	Diameter (D) and Length (L)	ø3.75 x L 10, 11.5, 13 mm ø3.77 x L 8.5 mm ø3.8 x L 8.5, 10, 11.5, 13, 15, 18 mm ø4.2 x L 10, 11.5, 13, 15, 18 mm ø4.25 x L 7, 8.5 mm ø4.6 x L 10, 11.5, 13, 15, 18 mm ø4.63 x L 8.5 mm ø4.65 x L 7 mm ø5.05 x L 10, 11.5, 13, 15, 18 mm ø5.08 x L 8.5 mm ø5.1 x L 7 mm
TSIV SA Implant	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.
	Material	Titanium Grade 4 (ASTM F67)
	Surface	SA surface treatment
	Diameter (D) and Length (L)	ø4.4 x L 18 mm ø4.8 x L 18 mm

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		ø5.25 x L 18 mm		
TS Scan Healing Abutment	Description	It is used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.		
	Material	Titanium Grade 4 (ASTM F67)		
	Diameter (D) and Length (L)	ø4.3 x L 5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.6 mm ø4.8 x L 5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.5 mm ø5.3 x L 5.5, 6.5, 7.5, 9.5, 11.5 mm ø6.3 x L 5.5, 6.5, 7.5, 9.5, 11.5 mm ø7.3 x L 5.5, 6.5, 7.5, 9.5 mm		
TS Scan Healing Abutment Screw	Description	It is used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.		
	Material	Titanium Alloy (ASTM F136)		
	Diameter (D) and Length (L)	ø2.2 x L 10, 11, 12, 14, 16 mm ø2.3 x L 8, 9, 10, 12, 14 mm		
SSII SA Implant	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.		
	Material	Titanium Grade 4 (ASTM F67)		
	Surface	SA surface treatment		
	Dimension	G/H	D	L
		1.8	4.8, 6.0	7, 8.5, 10, 11.5, 13, 15mm
		2.8	4.8, 6.0	7, 8.5, 10, 11.5, 13, 15mm
SSIII SA Implant	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.		
	Material	Titanium Grade 4 (ASTM F67)		
	Surface	SA surface treatment		
	Dimension	G/H	D	L
		0.8	4.8, 6.0	7 mm
		1.8	4.8, 6.0	7, 8.5, 10, 11.5, 13, 15 mm
		2.0	6.0	15.0 mm
		2.8	4.8, 6.0	7, 8.5, 10, 11.5, 13, 15 mm
SSIII SA Ultra-Wide Implant	Description	Intended to be surgically placed in the bone of the upper or lower jaw arches.		
	Material	Titanium Grade 4 (ASTM F67)		
	Surface	SA surface treatment		
	Dimension	G/H	D	L
		1.8	6.0	7, 8.5, 10, 11.5, 13 mm
		2.8	6.0	7, 8.5, 10, 11.5, 13 mm

6. Substantial Equivalence Matrix

These subject devices are adding additional dimensions to otherwise identical implant bodies cleared in past 510(k)s; therefore, indication for use, shape, connection structure, material, surface treatment, manufacturer and etc. are the same with predicate devices except dimension of additional products.

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1) TSIII SA Implant

	Subject device	Primary predicate device	Predicate device	Reference device	Remark
Device Name	TSIII SA Implant	TSIII SA Implant	TSIII SA Implant	External Hex Implants	Same
510(k) Number	-	K161604	K121995	K163634	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	NA	Same
Design				NA	Similar
Indication for Use	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant System is indicated 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. Products with diameter of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	Southern Implants' External Hex 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.	Same
Diameter (D)	ø3.75 x L 18, 20 mm	ø4.6 x L 18 mm	ø3.75 x L 10, 11.5,	ø 3.25 x L 8.5, 10,	Different

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and Length (L)	ø3.77 x L 7 mm ø4.25 x L 7 mm ø4.65 x L 7 mm ø5.45 x L 10, 11.5, 13, 15 mm ø5.48 x L 8.5 mm ø5.5 x L 7mm	ø5.05 x L 18 mm	13, 15 mm ø3.77 x L 8.5 mm ø4.2 x L 10, 11.5, 13, 15, 18 mm ø4.25 x L 7, 8.5 mm ø4.6 x L 10, 11.5, 13, 15 mm ø4.63 x L 8.5 mm ø4.65 x L 7 mm ø5.05 x L 10, 11.5, 13, 15 mm ø5.08 x L 8.5 mm ø5.1 x L 6.2, 7 mmø3.5 x L 8.5, 10, 11.5, 13, 15 mm ø4.2 x L 7, 8.5, 10, 11.5, 13, 15 mm ø4.4 x L 7, 8.5, 10, 11.5, 13, 15 mm ø4.9 x L 7, 8.5, 10, 11.5, 13, 15 mm	11.5, 13, 15, 18 mm ø 3.75 x L 7, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.0 x L 6, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.7 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 5.0 x L 6, 7, 8.5, 11.5, 13, 15, 18 mm ø 5.7 x L 10, 11.5, 13, 15, 18 mm ø 6.0 x L 7, 8.5, 10, 11.5, 13, 15 mm	
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	CP Titanium	Same
Surface	SA	SA	SA	Grit blasted Machine collar versions available	Same
Connection	Internal Hex	Internal Hex	Internal Hex	External Hex	Same
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	NA	Same
Shelf life	8 years	8 years	8 years	NA	Same
S.E.	**Similarities** Proposed TSIII SA Implant has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate TSIII SA Implant, K161604 and K121995. **Differences** The proposed device has different range of dimensions than predicate device. However, the added diameter is larger than predicate device, so it is more stable than predicate device. Although there is the additional of extended implant lengths of 20mm, additional length is included in dimension range of predicate device, K163634. In addition, since proposed device is compatible with the same abutment, it has same moment-arm as predicate devices, K161604 and K121995. ∴ The proposed TSIII SA Implant is substantially equivalent to the predicate devices.				

2) TSIII SA Implant (Non-Hex) Ø 3.2

	Subject Device	**Predicate Device**	**Remark**
Device Name	TSIII SA Implant (Non-Hex) Ø 3.2	TSIII SA Implant 3.2	Different
510(k) Number	-	K161604	-

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Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Same
Indication for Use	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	Same
Diameter (D) and Length (L)	ø3.2 x L 8.5, 10.0, 11.5, 13.0, 15.0 mm	ø3.2 x L 8.5, 10.0, 11.5, 13.0, 15.0 mm	Same
Connection	Non-Hex	Hex	Different
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
Surface	SA	SA	Same
Sterilization	Radiation Sterile	Radiation Sterile	Same
Shelf life	8 years	8 years	Same
S.E.	**Similarities** Proposed TSIII SA Implant (Non-Hex) Ø 3.2 has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate TSIII SA Implant 3.2 (K161604). **Differences** The proposed TSIII SA Implant (Non-Hex) Ø 3.2 is included in dimension range of predicate device and has the same diameter of the embedding plane according to the ISO14801. However, proposed TSIII SA Implant (Non-Hex) Ø 3.2 has non hexagon connection that is different from predicate TSIII SA Implant. Therefore, we conducted fatigue test according to ISO14801 and the test result does not show any significant difference in regard of mechanical strength. ∴ Proposed TSIII SA Implant (Non-Hex) Ø 3.2 and the predicate TSIII SA Implant 3.2 have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed TSIII SA Implant (Non-Hex) Ø 3.2 is substantially equivalent to the predicate device.		

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3) TSIII SA Implant (Non-Hex)

	Subject device	Primary predicate device	Predicate device	Remark
Device Name	TSIII SA Implant (Non-Hex)	TSIII SA Implant	TSIII SA Implant	Same
510(k) Number	-	K161604	K121995	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design				Similar
Indication for Use	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant System is indicated 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. Products with diameter of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	Same
Diameter (D) and Length (L)	ø3.75 x L 10, 11.5, 13 mm ø3.77 x L 8.5 mm ø3.8 x L 8.5, 10, 11.5, 13, 15, 18 mm ø4.2 x L 10, 11.5, 13, 15, 18 mm ø4.25 x L 7, 8.5 mm ø4.6 x L 10, 11.5, 13, 15, 18 mm ø4.63 x L 8.5 mm	ø4.6 x L 18 mm ø5.05 x L 18 mm	ø3.75 x L 10, 11.5, 13, 15 mm ø3.77 x L 8.5 mm ø4.2 x L 10, 11.5, 13, 15, 18 mm ø4.25 x L 7, 8.5 mm ø4.6 x L 10, 11.5, 13, 15 mm ø4.63 x L 8.5 mm ø4.65 x L 7 mm	Different

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	ø4.65 x L 7 mm ø5.05 x L 10, 11.5, 13, 15, 18 mm ø5.08 x L 8.5 mm ø5.1 x L 7 mm		ø5.05 x L 10, 11.5, 13, 15 mm ø5.08 x L 8.5 mm ø5.1 x L 6.2, 7 mmø3.5 x L 8.5, 10, 11.5, 13, 15 mm ø4.2 x L 7, 8.5, 10, 11.5, 13, 15 mm ø4.4 x L 7, 8.5, 10, 11.5, 13, 15 mm ø4.9 x L 7, 8.5, 10, 11.5, 13, 15 mm	
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Same
Surface	SA	SA	SA	Same
Connection	Internal Non-Hex	Internal Hex	Internal Hex	Different
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Same
Shelf life	8 years	8 years	8 years	Same
S.E.	**Similarities** Proposed TSIII SA Implant (Non-Hex) has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate TSIII SA Implant, K161604 and K121995. **Differences** The proposed TSIII SA Implant (Non-Hex) is included in dimension range of predicate device. Proposed TSIII SA Implant (Non-Hex) has non hexagon connection that is different from predicate TSIII SA Implant, but has the same diameter of the embedding plane as predicate device according to the ISO14801. Therefore, we selected the proposed device with the smallest diameter as the worst case and conducted fatigue test according to ISO14801, and the test result does not show any significant difference in regard of mechanical strength. ∴ Proposed TSIII SA Implant (Non-Hex) and the predicate TSIII SA Implant have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed TSIII SA Implant (Non-Hex) is substantially equivalent to the predicate device.			

4) TSIV SA Implant

	Subject Device	**Predicate Device**	**Reference device**	**Remark**
Device Name	TSIV SA Implant	TSIV SA Implant	External Hex Implants	Same
510(k) Number	-	K161604	K163634	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	NA	Same

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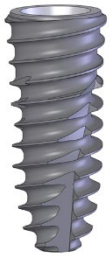
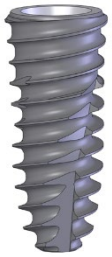
Design			NA	Same
Indication for Use	The Osstem Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	Southern Implants' External Hex 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.	Same
Diameter (D) and Length (L)	ø4.4 x L 18 mm ø4.8 x L 18 mm ø5.25 x L 18 mm	ø4.4 x L 7, 8.5, 10, 11.5, 13, 15 mm ø4.8 x L 7, 8.5, 10, 11.5, 13, 15 mm ø5.25 x L 7, 8.5, 10, 11.5, 13, 15 mm	ø 3.25 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 3.75 x L 7, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.0 x L 6, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.7 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 5.0 x L 6, 7, 8.5, 11.5, 13, 15, 18 mm ø 5.7 x L 10, 11.5, 13, 15, 18 mm ø 6.0 x L 7, 8.5, 10, 11.5, 13, 15 mm	Different
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	CP Titanium	Same
Surface	SA	SA	Grit blasted Machine collar versions	Same

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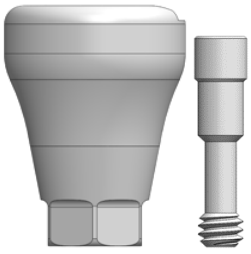
			available	
			External Hex	
Sterilization	Radiation Sterile	Radiation Sterile	NA	Same
Shelf life	8 years	8 years	NA	Same
S.E.	**Similarities** Proposed TSIV SA Implant has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate TSIV SA Implant (K161604). **Differences** There is the additional of extended implant lengths of 18mm, but additional length is included in dimension range of predicate device. In addition, since proposed device is compatible with the same abutment as predicate device, there is no difference in moment-arm, so the difference in length is not a factor affecting performance. Therefore, we didn't consider additional fatigue test according to ISO14801. ∴ Proposed TSIV SA Implant and the predicate TSIV SA Implant have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed TSIV SA Implant is substantially equivalent to the predicate device.			

5) TS Scan Healing Abutment

	Subject Device	**Predicate Device**	**Remark**
Device Name	TS Scan Healing Abutment	Healing Abutment	Different
510(k) Number	-	K161604	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Similar
Description	Used to make a natural soft tissue shape until setting up prosthetics. It is intended use to combine with implanted fixture after osseointegration then removing cover screw.	Used to make a natural soft tissue shape until setting up prosthetics. It is intended use to combine with implanted fixture after osseointegration then removing cover screw.	Same
Diameter (D) and Length (L)	ø4.3 x L 5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.6 mm ø4.8 x L 5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.5 mm ø5.3 x L 5.5, 6.5, 7.5, 9.5, 11.5 mm ø6.3 x L 5.5, 6.5, 7.5, 9.5, 11.5 mm ø7.3 x L 5.5, 6.5, 7.5, 9.5 mm	ø4.3 x L 7.5, 8.5, 9.5, 10.5, 11.5, 12.5, 13.5, 14.5 mm ø4.8 x L 7.5, 8.5, 9.5, 10.5, 11.5, 12.5, 13.5, 14.5 mm ø5.3 x L 8.5, 9.5, 10.5, 12.5, 14.5 mm ø6.3 x L 8.5, 9.5, 10.5, 12.5, 14.5 mm ø7.3 x L 8.5, 9.5, 10.5, 12.5, 14.5 mm	Different

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	Screw ø2.2 x L 10, 11, 12, 14, 16 mm ø2.3 x L 8, 9, 10, 12, 14 mm	ø8.3 x L 10.5 mm	
Material	Titanium Grade 4 (ASTMF67) * Screw: Titanium Alloy (ASTM F136)	Titanium Grade 4 (ASTMF67)	Different
Sterilization	Radiation Sterile	Radiation Sterile	Same
Shelf life	8 years	8 years	Same
S.E.	**Similarities** Proposed TS Scan Healing Abutment has same function and indication for use; and is made with same material with same manufacturing process by same manufacturer compared to that of the predicate Healing Abutment (K161604). **Differences** There is difference between proposed device and predicate on design. The predicate device has a screw-combined design compared to the proposed device. In addition, since TS Scan Healing Abutment is used temporarily to make natural soft tissue shape until setting up prosthetics, it does not require any performance. Therefore, we didn't consider additional performance testing. ∴ Proposed TS Scan Healing Abutment and the predicate Healing Abutment have common in function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed TS Scan Healing Abutment is substantially equivalent to the predicate device.		

6) SSII SA Implant

	Subject Device	**Predicate Device**	**Reference Device**	**Remark**
Device Name	SSII SA Implant	SSII SA Implant	External Hex Implants	Same
510(k) Number	-	K163557	K163634	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	NA	Same
Design			NA	Similar
Indication for Use	The Osstem Implant System is indicated 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	The Osstem Implant 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	Southern Implants' External Hex 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	Same

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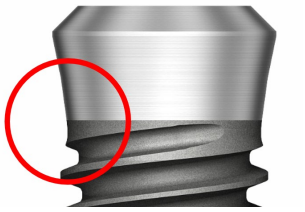
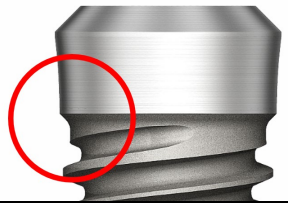
	restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	restorations, and finally or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra Wide Implant System is intended to be used in the molar region.	delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.	
Appearance			NA	Different
Dimension	ø 4.8 x L 7, 8.5, 10, 11.5, 13, 15 mm ø 6.0 x L 7, 8.5, 10, 11.5, 13, 15 mm	ø 4.1 x L 7, 8.5, 10, 11.5, 13, 15 mm ø 4.45 x L 7, 8.5, 10, 11.5, 13, 15 mm ø 4.9 x L 7, 8.5, 10, 11.5, 13, 15 mm ø 5.0 x L 6 mm	ø 3.25 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 3.75 x L 7, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.0 x L 6, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.7 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 5.0 x L 6, 7, 8.5, 11.5, 13, 15, 18 mm ø 5.7 x L 10, 11.5, 13, 15, 18 mm ø 6.0 x L 7, 8.5, 10, 11.5, 13, 15 mm	Different
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	CP Titanium	Same
Surface	SA	SA	Grit blasted Machine collar versions available	Same
Connection	Internal Octa	Internal Octa	External Hex	Different
Sterilization	Radiation Sterile	Radiation Sterile	NA	Same
Shelf life	8 years	8 years	NA	Same
S.E.	**Similarities** Proposed SSII SA Implant has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate SSII SA Implant (K163557). **Differences** In addition, since proposed device is compatible with the same abutment and has same moment-arm as			

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	predicate device, K163557. Proposed devices with the same combination of dimensions, except for gingival height only, are identical in all implanted parts. In addition, since the diameter of embedding plane is same as predicate device, we didn't consider additional fatigue test according to ISO14801. ∴ Therefore, the proposed SSII SA Implant is substantially equivalent to the predicate devices.

7) SSIII SA Implant

	Subject Device	**Predicate Device**	**Reference Device**	**Remark**
Device Name	SSIII SA Implant	SSIII SA Implant	External Hex Implants	Same
510(k) Number	-	K163557	K163634	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	NA	Same
Design			NA	Similar
Indication for Use	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant 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 finally or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra Wide Implant System is intended to be used in the molar region.	Southern Implants' External Hex 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.	Same

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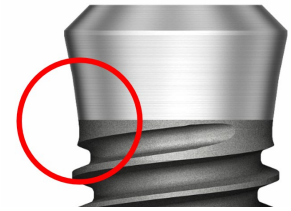
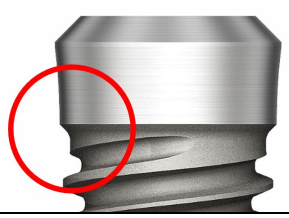
Appearance			NA	Different
Dimension	ø 4.8 x L 7, 8.5, 10, 11.5, 13, 15 mm ø 60 x L 7, 8.5, 10, 11.5, 13, 15 mm	ø 3.75 x L 8.5, 10, 11.5, 13 mm ø 4.25 x L 7, 8.5, 10, 11.5, 13 mm ø 4.6 x L 7, 8.5, 10, 11.5, 13 mm ø 5.0 x L 10, 11.5, 13 mm ø 5.05 x L 6, 7, 8.5 mm	ø 3.25 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 3.75 x L 7, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.0 x L 6, 8.5, 10, 11.5, 13, 15, 18, 20 mm ø 4.7 x L 8.5, 10, 11.5, 13, 15, 18 mm ø 5.0 x L 6, 7, 8.5, 11.5, 13, 15, 18 mm ø 5.7 x L 10, 11.5, 13, 15, 18 mm ø 6.0 x L 7, 8.5, 10, 11.5, 13, 15 mm	Different
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	CP Titanium	Same
Surface	SA	SA	Grit blasted Machine collar versions available	Same
Connection	Internal Octa	Internal Octa	External Hex	Same
Sterilization	Radiation Sterile	Radiation Sterile	NA	Same
Shelf life	8 years	8 years	NA	Same
S.E.	**Similarities** Proposed SSIII SA Implant has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate SSIII SA Implant (K163557). **Differences** There is the additional of extended implant lengths of 15mm, but additional length is included in dimension range of predicate device. In addition, since proposed device is compatible with the same abutment as predicate device, there is no difference in moment-arm, so the difference in length is not a factor affecting performance. Therefore, we didn't consider additional fatigue test according to ISO14801. Gingival height of the proposed device is smaller than predicate device, but the performance is not affected because it is a non-implantable part. Proposed device has a smaller surface area due to the difference in neck shape, but has a larger surface area compared to the predicate device SS2R4007S18, which has diameter Ø4.8 and length 7mm. In addition, since the diameter of embedding plane is same as predicate device, we didn't consider additional fatigue test according to ISO14801.			

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	∴ Proposed SSIII SA Implant and the predicate SSIII SA Implant have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed SSIII SA Implant is substantially equivalent to the predicate device.

8) SSIII SA Ultra-Wide Implant

	Subject Device	Predicate Device	Remark
Device Name	SSIII SA Ultra-Wide Implant	SSIII SA Ultra-Wide Implant	Same
510(k) Number	-	K163557	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Same
Design			Same
Indication for Use	The Osstem Implant System is indicated 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 Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Implant 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 finally or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra Wide Implant System is intended to be used in the molar region.	Same
Dimension	ø 6.0 x L 7, 8.5, 10, 11.5, 13 mm	ø 5.92 x L 11.5, 13 mm ø 5.95 x L 10 mm ø 5.96 x L 6, 8.5 mm ø 6.0 x L 7 mm ø 6.8 x L 7, 8.5, 10, 11.5, 13 mm ø 6.93 x L 6 mm	Different
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Same
Surface	SA	SA	Same
Connection	Internal Octa	Internal Octa	Same
Sterilization	Radiation Sterile	Radiation Sterile	Same
Shelf life	8 years	8 years	Same

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S.E.	**Similarities** Proposed SSIII SA Ultra-Wide Implant has same design, function and indication for use; and is made with same material with same manufacturing process (including surface treatment) by same manufacturer compared to that of the predicate SSIII SA Ultra-Wide Implant (K163557). **Differences** Gingival height of the proposed device is different from predicate device SSIII SA Ultra-Wide Implant (K163557), but the performance is not affected because it is a non-implantable part. In addition, since the diameter of embedding plane is same as predicate device, we didn't consider additional fatigue test according to ISO14801. ∴ Proposed SSIII SA Ultra-Wide Implant and the predicate SSIII SA Ultra-Wide Implant have common in design, function, indications for use, material, manufacturing process, manufacturer, etc.; therefore, the proposed SSIII SA Ultra-Wide Implant is substantially equivalent to the predicate SSIII SA Ultra-Wide Implant (K163557).

7. Summary of Non-clinical Performance Testing.

Below tests were performed on subject device:
- Fatigue Testing under the worst-case scenario according to ISO 14801:2016

Below tests were performed for predicate devices and leveraged for the subject device:
- Gamma Sterilization Validation Test on Implants according to ISO 11137-1,2,3 referenced in K121585
- Shelf-Life Test on Implants according to ASTM F1980 referenced in K121585
- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:1999, ISO 10993-6:2007, ISO 10993-10:2006, ISO 10993-11:2006 referenced in K121995
- Bacterial Endotoxin Test Report on implants according to ISO 10993-11:2006 and USP<151> referenced in K161604

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

Validation of the gamma irradiation process was previously conducted for the predicate device, K121585. There has been no change to the manufacturing or sterilization processes.

The Biocompatibility Test was conducted on the predicate device and leveraged for the subject device because both products are manufactured with same materials, manufacturer, manufacturing process etc. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.
The non-clinical testing result demonstrate that the subject device is substantially equivalent to the predicate device.

Osstem Implant System has SA (Sand blasted and Acid etched surface) surface treatment that is exactly same with the predicate devices, K121585. There has been no change to the manufacturing or surface treatment processes.

Fatigue testing was considered according to the FDA Guidance Document *Guidance for Industry and FDA Staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment* and ISO 14801 standard with the worst case scenario.
For proposed TSIII SA Implant (Non-Hex), fatigue testing was conducted according to ISO 14801:2016 Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants. The worst-case implant-abutment combination of the proposed device was chosen based on the FDA Guidance, ClassII Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. Test results demonstrate that the proposed devices perform as

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intended and support substantial equivalence to the predicate devices.

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.

8. Summary of Clinical Testing

No clinical studies are submitted.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Osstem Implant Co., Ltd. concludes that Osstem Implant System is substantially equivalent to the predicate devices as herein.