March 4, 2026

Osstem Implant Co., Ltd.
% Martin Shin
Assistant Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K251434
Trade/Device Name: Healing Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 27, 2025
Received: February 2, 2026

Dear Martin Shin:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.

Submission Number *(if known)*

K251434

Device Name

Healing Abutment System

Indications for Use *(Describe)*

The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.

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

K251434

Date: March 4, 2026

1. Company and Correspondent making the submission

- Submitter's Name	:	Osstem Implant Co., Ltd.
- Address	:	66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
- Contact	:	Ms. Yeseul Kang
- Phone	:	+82-70-4871-0216
- Correspondent's Name	:	Hiossen Inc.
- Address	:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact	:	Mr. Martin Shin
- Phone	:	+1-267-710-6714

2. Proposed Device

- Trade or (Proprietary) Name	:	Healing Abutment System
- Classification Name	:	Endosseous dental implant abutment
- Regulation Number	:	21CFR872.3630
- Devce Classification	:	Class II
- Classification Product Code	:	NHA

3. Predicated Device(s)

Primary Predicate		
K233194	Osstem Implant Co., Ltd.	TS Abutment System
Reference Device		
K222778	Osstem Implant Co., Ltd.	Osstem Implant System
K211109	Nobel Biocare AB	Healing Abutment Nobel Biocare N1™ TCC
K161604	Osstem Implant Co., Ltd.	OSSTEM Implant System
K160670	Osstem Implant Co., Ltd.	ET US SS Prosthetic system
K073247	Osstem Implant Co., Ltd.	US/SS/GS SYSTEM
K072642	Biomet 3i LLC	Certain BellaTek Encode Healing Abutment
K062051	Osstem Implant Co., Ltd.	SS SYSTEM
K062030	Osstem Implant Co., Ltd.	US SYSTEM

4. Description

Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement. And Scan Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement. The device incorporates design features intended to facilitate intraoral digital scanning.

The specifications of the proposed device are as follows.

Device	Content	
TS Healing Abutment	Description	The Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement.
	Material	Titanium Grade 4 (ASTM F67)
	Diameter (D) and Height (H)	Ø4.3 x H 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0 mm Ø4.8 x H 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 mm Ø5.3 x H 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0 mm Ø6.3 x H 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0 mm Ø7.3 x H 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0 mm Ø8.3 x H 3.0, 4.0, 5.0, 6.0, 7.0 mm Ø9.3 x H 3.0, 4.0, 5.0 mm
SS Healing Abutment	Description	The Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement.
	Material	Titanium Grade 4 (ASTM F67)
	Diameter (D) and Height (H)	Ø5.5 x H 2.0, 3.0, 4.0, 5.5, 7.0 mm Ø6.7 x H 3.0, 4.0, 5.5 mm
US Healing Abutment	Description	The Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement.
	Material	Titanium Grade 4 (ASTM F67)
	Diameter (D) and Height (H)	Ø4.0 x H 4.1, 5.1, 6.6, 8.1 mm Ø4.13 x H 4.1, 6.6, 8.1 mm Ø5.0 x H 3.1, 4.1, 5.1, 6.6, 8.1 mm Ø5.13 x H 4.1, 6.6 mm Ø6.0 x H 3.1, 4.1, 5.1, 6.6, 8.1 mm Ø7.0 x H 3.1, 4.1, 5.1, 6.6 mm
SS Scan Healing Abutment	Description	The Scan Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement. The device incorporates design features intended to facilitate intraoral digital scanning.
	Material	Titanium Grade 4 (ASTM F67)
	Diameter (D) and Length (L)	Ø5.3 x L 4.0, 5.0, 6.0, 7.0 mm Ø6.3 x L 5.35, 6.35, 7.35 mm
SS Scan Healing Abutment Screw	Description	It is used to connect SS Scan Healing Abutment with implant
	Material	Ti-6Al-4V (ASTM F136)
	Diameter (D) and Length (L)	Ø2.3 x L 6.3, 7.3, 8.3, 9.3 mm
US Scan Healing Abutment	Description	The Scan Healing Abutment is intended for temporary connection to a dental implant to support healing of the surrounding soft tissue prior to prosthetic placement. The device incorporates design

		features intended to facilitate intraoral digital scanning.
	Material	Titanium Grade 4 (ASTM F67)
	Diameter (D) and Length (L)	Ø4.3 x L 4.1, 6.1, 8.1 mm Ø5.3 x L 4.1, 6.1, 8.1 mm Ø6.3 x L 4.1, 6.1 mm
US Scan Healing Abutment Screw	Description	It is used to connect US Scan Healing Abutment with implant
	Material	Ti-6Al-4V (ASTM F136)
	Diameter (D) and Length (L)	Ø2.2 x L 7.0, 9.0, 11.0 Ø2.3 x L 7.0, 9.0, 11.0 Ø2.45 x L 7.0, 9.0, 11.0

5. Substantial Equivalence Matrix

1) TS Healing Abutment

	Subject Device	**Primary Predicate**	**Reference Device 1**	**Reference Device 2**	**Comparison**
Device Name	TS Healing Abutment	TS Healing Abutment	TS Healing Abutment	Healing Abutment Nobel Biocare N1™ TCC	-
510(k) Number	-	K233194	K161604	K211109	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Nobel Biocare AB	-
Design					The same design as the primary predicate and references #1
Indication for Use (Intended Use)	The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.	The OSSTEM Abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The Osstem Implant System 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 Fixture System is intended to be used in the molar region. Products with diameter of less than 3.25mm should be used	Healing Abutments are intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.	The same indication for use as reference #2, described in similar terms

<table>
<tr><td></td><td></td><td></td><td>exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.</td><td></td><td></td></tr>
<tr><td>Diameter (D) and Height (H)</td><td>
<table>
<tr><th>D(Ø)</th><th>H</th></tr>
<tr><td>4.3</td><td>2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0</td></tr>
<tr><td>4.8</td><td>3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0</td></tr>
<tr><td>5.3</td><td>3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0</td></tr>
<tr><td>6.3</td><td>3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0</td></tr>
<tr><td>7.3</td><td>3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0</td></tr>
<tr><td>8.3</td><td>3.0, 4.0, 5.0, 6.0, 7.0, 8.0</td></tr>
<tr><td>9.3</td><td>3.0, 4.0, 5.0</td></tr>
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</td><td>
<table>
<tr><th>D(Ø)</th><th>H</th></tr>
<tr><td>4.3</td><td>2.0, 6.0, 8.0</td></tr>
<tr><td>4.8</td><td>6.0, 8.0, 10.0</td></tr>
<tr><td>5.3</td><td>6.0, 8.0, 10.0, 11.0, 12.0</td></tr>
<tr><td>6.3</td><td>6.0, 8.0</td></tr>
<tr><td>7.3</td><td>6.0, 8.0</td></tr>
<tr><td>8.3</td><td>6.0, 8.0</td></tr>
<tr><td>9.3</td><td>5.0, 6.0, 8.0</td></tr>
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<tr><th>D(Ø)</th><th>H</th></tr>
<tr><td>4.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr>
<tr><td>4.8</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr>
<tr><td>5.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr>
<tr><td>6.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr>
<tr><td>7.3</td><td>3.0, 4.0, 5.0, 7.0, 9.0</td></tr>
<tr><td>8.3</td><td>5.0</td></tr>
</table>
</td><td>
<table>
<tr><th>D(Ø)</th><th>H</th></tr>
<tr><td>4.0</td><td>3.0, 5.0, 7.0</td></tr>
<tr><td>4.5</td><td>3.0, 5.0, 7.0</td></tr>
</table>
</td><td>The range of implant lengths falls within that of the primary predicate and reference #1 and #2</td></tr>
<tr><td>Compatible Device</td><td>Osstem TS Implant
Cleared in K121585, K121995, K161604, K163088, and K222778</td><td>Osstem TS Implant
Cleared in K121585, K121995, K161604, K163088, and K222778</td><td>Osstem TS Implant
Cleared in K121585, K121995, K161604, K163088, and K222778</td><td>N1™ TiUltra™ TCC Implant
Cleared in K211109</td><td>Same as primary predicat and reference #1</td></tr>
<tr><td>Material</td><td>Titanium Grade 4
(ASTM F67)</td><td>Titanium Grade 4
(ASTM F67)</td><td>Titanium Grade 4
(ASTM F67)</td><td>Titanium- aluminum-vanadium alloy (ASTM F136)</td><td>Same as primary predicat and reference #1</td></tr>
<tr><td>Packaging</td><td>1st – Blister & Tyvek
2nd – Carton Box</td><td>1st – Ampoule
2nd – Blister & Tyvek
3rd – Carton Box</td><td>1st – Ampoule
2nd – Blister & Tyvek
3rd – Carton Box</td><td>Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.</td><td>Equivalent sterile barrier system (identical blister & Tyvek sealing area)</td></tr>
<tr><td>Sterilization</td><td>Gamma sterilization</td><td>Gamma sterilization</td><td>Gamma sterilization</td><td>Gamma sterilization</td><td>Same</td></tr>
</table>

Substantial Equivalence	The proposed device, TS Healing Abutment, is manufactured using the same material, manufacturing process, and design characteristics as the primary predicate device, the TS Healing Abutment (K233194). Additionally, the proposed deivce has an equivalent intended use and similar design characteristics compared to the referece devie, the Healing Abutment Nobel Biocare N1™ TCC. Differences between the subject and predicate devices are limited to the range of available diameters and lengths, implant compatibility, and packaging. The dimensional range of the subject device remains within that of the primary predicate and reference devices and does not affect safety or effectiveness, as the device is intended solely for soft tissue healing and does not perform a load-bearing function. Although the packaging differs, the sterile barrier system such as packaging materials and sealing method is identical. Based on packaging validation using a worst-case representative device and the material stability of titanium, the established shelf life does not raise new safety or effectiveness concerns. The compatible implant for the subject device differs from those of the predicate devices(K211109); however, the proposed device has the same compatible device ,Osstem TS Implant that has been previously cleared by the FDA under K121585, K121995, K161604, K163088, and K222778 Therefore, the proposed TS Healing Abutment is substantially equivalent to the predicate devices.

2) SS Healing Abutment

	Subject Device	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Comparison**
Device Name	SS Healing Abutment	SS Healing Abutment	SS Healing Abutment	Healing Abutment Nobel Biocare N1™ TCC	-
510(k) Number	-	K062051	K073247	K211109	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Nobel Biocare AB	-
Design					The same design as the references #1 and #2
Indication for Use (Intended Use)	The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.	SS 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	The US/SS/GS System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support	Healing Abutments are intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.	The same indication for use as reference #3, described in similar terms

		for fixed bridgework. SS System is for single stage surgical procedures.	for fixed bridgework. The US/SS/GS Fixture System is for one and two stage surgical procedures. It is not for immediate load.		
Diameter (D) and Height (H)	**D(Ø)** / **H** 5.5 / 2.0, 3.0, 4.0, 5.5, 7.0 6.7 / 3.0, 4.0, 5.5	**D(Ø)** / **H** 5.5 / 2.0, 3.0, 4.0 6.7 / 3.0	**D(Ø)** / **H** 5.5 / 5.5 6.7 / 4.0, 5.5	**D(Ø)** / **H** 4.0 / 3.0, 5.0, 7.0 4.5 / 3.0, 5.0, 7.0	The range of implant lengths falls within that of references 1 and #2
Compatible Device	Osstem SS Implant Cleared in K163557 and K222778	Osstem SS Implant Cleared in K163557 and K222778	Osstem SS Implant Cleared in K163557 and K222778	N1™ TiUltra™ TCC Implant Cleared in K211109	Same as references #1 and #2
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium- aluminum-vanadium alloy (ASTM F136)	Same as references #1 and #2
Packaging	1st – Blister & Tyvek 2nd – Carton Box	1st – Ampoule 2nd – Blister & Tyvek 3rd – Carton Box	1st – Ampoule 2nd – Blister & Tyvek 3rd – Carton Box	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Equivalent sterile barrier system (identical blister & Tyvek sealing area)
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Same
Substantial Equivalence	The proposed device, SS Healing Abutment, is manufactured using the same material, manufacturing process, and design characteristics as reference devices 1 and 2, the SS Healing Abutment (K062051 and K073247). Additionally, the proposed deivce has an equivalent intended use and similar design characteristics compared to the referece devie 3, the Healing Abutment Nobel Biocare N1™ TCC. Differences between the subject and predicate devices are limited to the range of available diameters and lengths, implant compatibility, and packaging. The dimensional range of the subject device remains within that of the primary predicate and reference devices and does not affect safety or effectiveness, as the device is intended solely for soft tissue healing and does not perform a load-bearing function. Although the packaging differs, the sterile barrier system such as packaging materials and sealing method is identical are identical Based on packaging validation using a worst-case representative device and the material stability of titanium, the established shelf life does not raise new safety or effectiveness concerns. The compatible implant for the subject device differs from those of the predicate devices(K211109); however, the proposed device has the same compatible				

	device ,Osstem SS Implant that has been previously cleared by the FDA under K163557 and K222778. Therefore, the proposed SS Healing Abutment is substantially equivalent to the predicate devices.

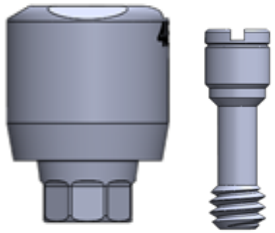
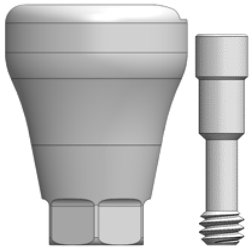
3) US Healing Abutment

	Subject Device	**Reference Device 1**	**Reference Device 2**	**Reference Device 3**	**Comparison**
Device Name	US Healing Abutment	US Healing Abutment	US Healing Abutment	Healing Abutment Nobel Biocare N1™ TCC	-
510(k) Number	-	K160670	K062030	K211109	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Nobel Biocare AB	-
Design					The same design as the references #1 and #2
Indication for Use (Intended Use)	The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.	The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	US Implant System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. US Implants are for two stage surgical procedures.	Healing Abutments are intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.	The same indication for use as reference #3, described in similar terms
Diameter (D) and Height (H)	**D(Ø)** / **H** 4.0 / 4.1, 5.1, 6.6, 8.1 4.13 / 4.1, 6.6, 8.1 5.0 / 3.1, 4.1, 5.1, 6.6, 8.1 5.13 / 4.1, 6.6, 8.1 6.0 / 3.1, 4.1, 5.1, 6.6, 8.1 7.0 / 3.1, 4.1, 5.1, 6.6	**D(Ø)** / **H** 4.13 / 4.1, 6.6, 8.1 5.0 / 4.1, 6.6 5.1 / 4.1, 6.6 5.13 / 4.1, 6.6	**D(Ø)** / **H** 4.0 / 4.1, 6.6 5.0 / 3.1, 4.1, 5.1, 6.6, 8.1 6.0 / 3.1, 4.1, 5.1, 6.6, 8.1 7.0 / 3.1, 4.1, 5.1, 6.6	**D(Ø)** / **H** 4.0 / 3.0, 5.0, 7.0 4.5 / 3.0, 5.0, 7.0	The range of implant lengths falls within that of references 1 and #2
Compatible Device	Osstem US Implant Cleared in K161103	Osstem US Implant Cleared in K161103	Osstem US Implant Cleared in K161103	N1™ TiUltra™ TCC Implant Cleared in K211109	Same as references #1 and #2

Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium-aluminum-vanadium alloy (ASTM F136)	Same as references #1 and #2
Packaging	1st – Blister & Tyvek 2nd – Carton Box	1st – Ampoule 2nd – Blister & Tyvek 3rd – Carton Box	1st – Ampoule 2nd – Blister & Tyvek 3rd – Carton Box	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Equivalent sterile barrier system (identical blister & Tyvek sealing area)
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Same
Substantial Equivalence	The proposed device, US Healing Abutment, is manufactured using the same material, manufacturing process, and design characteristics as reference devices 1 and 2, the US Healing Abutment (K160670 and K062030). Additionally, the proposed deivce has an equivalent intended use and similar design characteristics compared to the referece devie 3, the Healing Abutment Nobel Biocare N1™ TCC. Differences between the subject and predicate devices are limited to the range of available diameters and lengths, implant compatibility, and packaging. The dimensional range of the subject device remains within that of the primary predicate and reference devices and does not affect safety or effectiveness, as the device is intended solely for soft tissue healing and does not perform a load-bearing function. Although the packaging differs, the sterile barrier system such as packaging materials and sealing method is identical are identical Based on packaging validation using a worst-case representative device and the material stability of titanium, the established shelf life does not raise new safety or effectiveness concerns. The compatible implant for the subject device differs from those of the predicate devices(K211109) ; the proposed device has the same compatible device ,Osstem US Implant has been previously cleared by the FDA under K161103. Therefore, the proposed US Healing Abutment is substantially equivalent to the predicate devices.				

4) SS Scan Healing Abutment

	Subject Device	**Reference Device 1**	**Reference Device 2**	**Comparison**
Device Name	SS Scan Healing Abutment	TS Scan Healing Abutment	Certain BellaTek Encode Healing Abutment	-
510(k) Number	-	K222778	K072642	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Biomet 3i LLC	-

Design				The similar design as the reference devices
Indication for Use (Intended Use)	The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.	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.	Biomet 3i Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained. Restorative Components: • Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing. • Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics. • Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.	The same indication for use as reference device 2, described in similar terms

<table>
<tr>
<td>Diameter (D) and Length (L)</td>
<td>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
<tr><td>5.3</td><td>4.0, 5.0, 6.0, 7.0</td></tr>
<tr><td>6.3</td><td>5.35, 6.35, 7.35</td></tr>
</table>
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<table>
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</td>
<td>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
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<tr><td>4.8</td><td>5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.5</td></tr>
<tr><td>5.3</td><td>5.5, 6.5, 7.5, 9.5, 11.5</td></tr>
<tr><td>6.3</td><td>5.5, 6.5, 7.5, 9.5, 11.5</td></tr>
<tr><td>7.3</td><td>5.5, 6.5, 7.5, 9.5</td></tr>
</table>
<u>Screw</u>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
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<tr><td>2.3</td><td>8.0, 9.0, 10.0, 12.0, 14.0</td></tr>
</table>
</td>
<td>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
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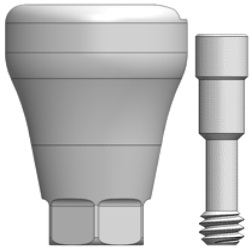
<tr><td>5.0</td><td>3.0, 4.0, 6.0, 8.0</td></tr>
<tr><td>6.0</td><td>3.0, 4.0, 6.0, 8.0</td></tr>
</table>
<u>Screw</u>
Dimensional information is not provided in the 510(k) Summary.
</td>
<td>The range of implant lengths falls within that of the reference devices</td>
</tr>
<tr><td>Compatible Device</td><td>Osstem SS Implant
Cleared in K163557 and K222778</td><td>Osstem TS Implant
Cleared in K121585, K121995, K161604, K163088, and K222778</td><td>Biomet 3i Dental Implant System
Cleared in K072363</td><td>Differences for each connection</td></tr>
<tr><td>Material</td><td>Titanium Grade 4
(ASTM F67)
* Screw: Titanium Alloy (ASTM F136)</td><td>Titanium Grade 4
(ASTM F67)
* Screw: Titanium Alloy (ASTM F136)</td><td>Titanium Alloy (ASTM F136)</td><td>Same as reference device 1</td></tr>
<tr><td>Packaging</td><td>1st – Ampoule
2nd – Blister & Tyvek
3rd – Carton Box</td><td>1st – Ampoule
2nd – Blister & Tyvek
3rd – Carton Box</td><td>Packaging information is not provided in the 510(k) Summary.</td><td>Same as reference device 1</td></tr>
<tr><td>Sterilization</td><td>Gamma sterilization</td><td>Gamma sterilization</td><td>Gamma sterilization</td><td>Same</td></tr>
<tr><td>Substantial Equivalence</td><td colspan="4">The proposed device, SS Scan Healing Abutment, has an equivalent intended use and similar design characteristics compared to the reference device 2, Certain BellaTek Encode Healing Abutment. Additionally, the proposed device is manufactured using the same material, manufacturing process, and design characteristics as the reference device 1, the TS Scan Healing Abutment.

The subject device differs only in the range of available dimesion (diameters& lengths), design features (groove and scan marker) for intraoral scanning, as well as in implant compatibility. However, the dimensional range remains within that of the reference devices, and these differences do not raise new safety and effectiveness concerns, as the device is intended for soft tissue healing and does not perform a load-bearing or mechanical function. Design features for intraoral scanning is ancillary design features to identify orientation of device during intraoral scanning. It does not alter fundamental indication for use.
The compatible implant for the subject device differs from those of the predicate devices; however, the compatible Osstem SS Implant has been previously cleared by the FDA under K163557 and K222778.

Therefore, the proposed SS Scan Healing Abutment is substantially equivalent to the predicate devices.</td></tr>
</table>

5) US Scan Healing Abutment

	Subject Device	**Reference Device 1**	**Reference Device 2**	**Comparison**
Device Name	US Scan Healing Abutment	TS Scan Healing Abutment	Certain BellaTek Encode Healing Abutment	-
510(k) Number	-	K222778	K072642	-
Manufacturer	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd	Biomet 3i LLC	-
Design				The similar design as the reference devices
Indication for Use (Intended Use)	The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.	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.	Biomet 3i Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained. Restorative Components: • Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing. • Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics. • Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.	The same indication for use as reference device 2, described in similar terms

<table>
<tr>
<td>Diameter (D) and Length (L)</td>
<td>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
<tr><td>4.3</td><td>4.1, 6.1, 8.1</td></tr>
<tr><td>5.3</td><td>4.1, 6.1, 8.1</td></tr>
<tr><td>6.3</td><td>4.1, 6.1, 8.1</td></tr>
</table>
<u>Screw</u>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
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<tr><th>D(Ø)</th><th>L</th></tr>
<tr><td>4.3</td><td>5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.6</td></tr>
<tr><td>4.8</td><td>5.5, 5.6, 6.5, 6.6, 7.5, 7.6, 9.5, 9.6, 11.5</td></tr>
<tr><td>5.3</td><td>5.5, 6.5, 7.5, 9.5, 11.5</td></tr>
<tr><td>6.3</td><td>5.5, 6.5, 7.5, 9.5, 11.5</td></tr>
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<table>
<tr><th>D(Ø)</th><th>L</th></tr>
<tr><td>2.2</td><td>10.0, 11.0, 12.0, 14.0, 16.0</td></tr>
<tr><td>2.3</td><td>8.0, 9.0, 10.0, 12.0, 14.0</td></tr>
</table>
</td>
<td>
<table>
<tr><th>D(Ø)</th><th>L</th></tr>
<tr><td>3.4</td><td>3.0, 4.0, 6.0, 8.0</td></tr>
<tr><td>4.1</td><td>3.0, 4.0, 6.0, 8.0</td></tr>
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</table>
<u>Screw</u>
Dimensional information is not provided in the 510(k) Summary.
</td>
<td>The range of implant lengths falls within that of the reference devices</td>
</tr>
<tr>
<td>Compatible Device</td>
<td>Osstem US Implant
Cleared in K161103</td>
<td>Osstem TS Implant
Cleared in K121585, K121995, K161604, K163088, and K222778</td>
<td>Biomet 3i Dental Implant System
Cleared in K072363</td>
<td>Differences for each connection</td>
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<tr>
<td>Material</td>
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(ASTM F67)
* Screw: Titanium Alloy (ASTM F136)</td>
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* Screw: Titanium Alloy (ASTM F136)</td>
<td>Titanium Alloy
(ASTM F136)</td>
<td>Same as reference device 1</td>
</tr>
<tr>
<td>Packaging</td>
<td>1st – Ampoule
2nd – Blister & Tyvek
3rd – Carton Box</td>
<td>1st – Ampoule
2nd – Blister & Tyvek
3rd – Carton Box</td>
<td>Packaging information is not provided in the 510(k) Summary.</td>
<td>Same as reference device 1</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Gamma sterilization</td>
<td>Gamma sterilization</td>
<td>Gamma sterilization</td>
<td>Same</td>
</tr>
<tr>
<td>Substantial Equivalence</td>
<td colspan="4">The proposed device, US Scan Healing Abutment, has equivalent intended use and similar design characteristics compared to the reference device 2, Certain BellaTek Encode Healing Abutment. Additionally, the proposed device is manufactured using the same material, manufacturing process, and design characteristics as the reference device 1, the TS Scan Healing Abutment.

The subject device differs only in the range of available dimesion (diameters& lengths), design features (groove and scan marker) for intraoral scanning, as well as in implant compatibility. However, the dimensional range remains within that of the reference devices, and these differences do not raise new safety and effectiveness concerns, as the device is intended for soft tissue healing and does not perform a load-bearing or mechanical function. Design features for intraoral scanning is ancillary design features to identify orientation of device during intraoral scanning. It does not alter fundamental indication for use.
The compatible implant for the subject device differs from those of the predicate devices; however, the compatible Osstem US Implant has been previously cleared by the FDA under K161103.

Therefore, the proposed US Scan Healing Abutment is substantially equivalent to the predicate devices.</td>
</tr>
</table>

6. Indications for Use

The Healing Abutment System is indicated for temporary connection to a dental implant to support healing of the surrounding soft tissue.

7. Summary of Non-clinical Performance Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence.

Biocompatibility Evaluation
The biocompatibility of the subject devices was evaluated in accordance with ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and the FDA guidance, "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".
The following evaluations were performed:
- Biological Risk Assessment per ISO 10993-1

The subject devices are manufactured from commercially pure titanium and titanium alloy with a long history of safe clinical use and have identical materials and manufacturing processes as the predicate devices. Based on risk assessment and chemical characterization, no new issues regarding biocompatibility were identified, and no additional biocompatibility testing was required.

Sterilization Validation and Shelf-life
The subject devices are sterilized by gamma irradiation. Sterilization validation for the predicate devices was performed in accordance with ISO 11137-1, ISO 11137-2, and ISO 11137-3, establishing a Sterility Assurance Level (SAL) of 10^{-6} using the VDmax 25 method.
The subject devices are manufactured using the same materials, manufacturing processes, packaging system, and sterilization modality as the predicate devices, and do not represent a new worst-case condition. Therefore, the predicate sterilization validation is considered applicable, and additional validation was not required.
The Healing Abutment System is manufactured from medical-grade titanium and titanium alloy, which are well known to be chemically stable and not susceptible to material degradation over time. Accordingly, material aging is not expected to impact on the sterility or performance of the device throughout the labeled shelf life.

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 Clnical Testing

No clinical studies are submitted.

9. Conclusion

The Healing Abutment System has the same intended use and similar design characteristics as the predicate and reference devices. The subject devices are manufactured using identical materials (commercially pure titanium and titanium alloy), manufacturing processes, sterilization method, and packaging system as the

predicate devices.

Differences between the subject and predicate devices are limited to dimensional ranges (diameter and length), implant compatibility, packaging appearance, and additional scan-related design features (e.g., groove or scan marker). The dimensional ranges remain within those of the predicate devices, and the devices are intended for soft tissue healing only and do not perform a load-bearing function.

Biological risk assessment in accordance with ISO 10993-1, as well as sterilization validation and shelf-life evaluation in accordance with ISO 11137-1, -2, and -3, confirmed that the differences do not raise new safety or effectiveness concerns.

Based on the similarities in intended use, technological characteristics, materials, and the supporting test results, the subject Healing Abutment System is considered substantially equivalent to the predicate devices.