May 4, 2018

TruAbutment Inc.
c/o April Lee
Consultant
Withus Group Inc.
106 Superior
Irvine, California 92620

Re: K172100
Trade/Device Name: URIS OMNI System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 3, 2018
Received: April 5, 2018

Dear April 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172100

Device Name
URIS OMNI System

Indications for Use *(Describe)*
URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

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

This 510(k) Summary is being submitted in accordance with requirement of 21 CFR part 807.92

Submitter:
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Device Information:
Device Name: URIS OMNI System
Classification Name: Endosseous Dental Implant
Classification: Class II
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation number: 21 CFR 872.3640
Date Prepared: 05/04/2018

Predicate Device
- Primary Predicate Device:
  - TS Fixture System (K121995) by Osstem Implant Co., Ltd.

- Reference Devices:
  - CMI Implant IS II active (K120503) by Neobiotech Co., Ltd.
  - Oneplant Dental Implant System (K081748) by Warantec Co., Ltd.
  - IH Implant System (K153521) by Sewon Medix Inc.
  - HU/HS/HG Prosthetic System(K081575) by Osstem Implant Co., Ltd.
  - OSSTEM Implant System – Abutment (K161689) by Osstem Implant Co., Ltd.
  - Transfer & Angled Abutment (K153015) by Osstem Implant Co., Ltd.
  - Straumann RC Temporary Abutments (K093027) by Straumann USA

Device Description
URIS OMNI System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI and the OMNI Tapered, with corresponding cover screws, healing abutments and prosthetic abutments. The OMNI Tapered implant has a tapered wall with a single thread design. The OMNI is straight walled with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have two platform sizes, Narrow (Ø 3.5 mm) and Regular (Ø 4.0 – Ø 6.5 mm). Both implant lines share the following diameters and lengths:

Ø 3.5 x 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 4.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 5.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 5.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
Ø 6.0 x 7, 8.5, 10mm (L)
Ø 6.5 x 7, 8.5, 10mm (L).

URIS Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of Cover screw, Healing abutment, D-Basis Abutment-direct type, D-basis abutment-cemented type, Angled abutment, Milling abutment, Temporary abutment, and Abutment screw. The surface of cover screw and healing abutment are anodized in yellow and green.

Device Component	Diameters (Ø)	Lengths	Angulation
Cover Screw	2.78/3.48mm	4.875/5.375mm	-
Healing Abutments	4.0/4.5/5.5/6.5/7.5mm	Cuff Height: 1.0mm~5.0mm	-

D-Basis Abutment-direct type	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
D-basis abutment-cemented type	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Angled abutment	4.0/ 4.5/5.5mm	Cuff Height: 2.0mm~5.0mm	17°
Milling abutment	4.0/5.0/6.0/7.0mm	Hex Type: 14.1/14.85mm Non-Hex Type: 13.9/14.85mm	-
Temporary abutment	3.7 / 4.3mm	Cuff Height: 1.0mm~3.0mm	-
Abutment screw	1.9/2.3mm	7.2/7.7mm	-

Fixtures and cover screw are provided sterile and other prosthetics are provided non-sterile. All non-sterile products must be sterilized by end users before use.

Indication for Use

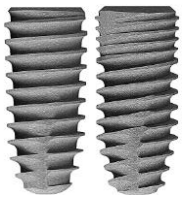
URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Summary of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material, design, dimension, connection, functions and surface treatments. Comparison demonstrating Substantial Equivalence follows at the end of this section.

URIS Fixture

	Subject Device	**Primary Predicate Device**	**Reference Devices**	
510K Number	K172100	K121995	K120503	K081748
Device Name	URIS OMNI System	TS Fixture System	CMI Implant IS II active	Oneplant Dental Implant System
Manufacturer	TruAbutment Co., Ltd.	OSSTEM Implant Co., Ltd.	Neobiotech Co., Ltd.	WARANTEC Co., Ltd.
Indications for Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The TS 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. TS Fixture System is compatible with abutment in the ET/SS Implant System.	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.	ONEPLANT is designed for use in dental implant Surgery. These are intended for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, screw retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.

Design				
Structure	- Internal Hex-connected - Submerged Fixture	- Internal Hex-connected - Submerged Fixture - Tapered body shape and straight body shape - 4-sided cutting edge with self-tapping	N/A	- Internal Connection - Morse Taper - Internal Octagon
Body Diameter(D)	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm	TSII SA Fixture: 3.5, 4.2, 4.4, 4.9 TSIII SA Fixture: 3.75, 3.77, 4.2, 4.25, 4.6, 4.63, 4.65, 5.05, 5.08, 5.1	3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0mm	3.3, 3.6,4.3, 5.3mm
Length (mm)	7, 8.5, 10, 11.5, 13, 14.5mm	7.0~15mm	7.0/7.3/8.5/10.0/11.5/13.0/15.0mm	8.5, 10, 11.5, 13, 15mm
Material of Fixture	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)
Surface	Sand-blasted, Large grit, Acid-etched (S.L.A)	SA (Sandblasting and Acid etching)	Sand-blasted, Large grit, Acid-etched (S.L.A)	N/A
Sterilization	Gamma Sterilization	Radiation Sterile	Gamma Sterilization	Gamma Sterilization
Shelf Life	5years	8years	N/A	N/A
Implant Body Features	Threaded	Threaded	Threaded	Threaded
Product Code	DZE	DZE	DZE	DZE
SE	The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material, design, dimension, connection, functions and surface treatments. The URIS Implant system is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-food endosseous dental implants and endosseous dental implant abutments. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.			

URIS Abutments

	Subject Device	Reference Devices	
Part Name	**Healing Abutment**	**Healing Abutment**	**Healing Abutment**
Design			
Applicant	TruAbutment Korea Co., Ltd.	Sewon Medix Inc.	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI System	IH Prosthetic System	HU/HS/HG Prosthetic System
510(K) No.	K172100	K153521	K081575
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or internal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	HU/HS/HG Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	4.0/4.5/5.5/6.5/7.5mm	4.0/4.5/5.0/5.5/6.0/6.5mm	N/A
Surface Treatment	Anodizing (Yellow, Green)	None	N/A
Sterile	Non-sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K153521, K081575) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter. Therefore, the subject device is substantially equivalent to the currently cleared devices.		

	Subject Device	Reference Devices	
Part Name	**D Basis Abutment - Direct Type**	**Solid Abutment**	**Rigid Abutment**
Design			
Applicant	TruAbutment Korea Co., Ltd.	Sewon Medix Inc.	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI System	IH Prosthetic System	OSSTEM Implant System - Abutment
510(K) No.	K172100	K153521	K161689
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or internal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	4.0/4.5/5.5/6.5mm	4.0/4.5/5.0/5.5/6.0/6.5/7.0	4.0, 4.6, 5.0, 6.0, 7.0mm
Lengths	G/H :1.0/2.0/3.0/4.0/5.0/6.0 Post : 4.0/5.5/7.0	G/H :1.0/1.5/2.0/2.5/3.0/3.5/ 4.0/4.5/5.0 Post: 4.0/5.5/7.0	10, 10.4, 11, 11.4, 11.5, 11.9, 12, 12.4, 12.5, 12.9, 13, 13.4, 13.5, 13.9, 14, 14.4, 14.5, 14.9, 15, 15.4, 15.5, 15.9, 16, 16.4, 17, 17.4
Surface Treatment	None	Machine or TiN	N/A
Sterile	Non-sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K153521, K161689) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter and lengths. Therefore, the subject device is substantially equivalent to the currently cleared devices.		

	Subject Device	Reference Devices	
Part Name	**D Basis Abutment-Cemented Type**	**Transfer Abutment**	**Cement Abutment**
Design			
Applicant	TruAbutment Korea Co., Ltd.	OSSTEM Implant Co., Ltd.	Sewon Medix Inc.
Trade Name	URIS OMNI System	Transfer & Angled Abutment	IH Prosthetic System
510(K) No.	K172100	K153015	K153521
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Transfer & Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or internal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.
Diameters	4.0/4.5/5.5/6.5mm	4.0mm	4.5/5.0/5.5/6.0 /6.5
Lengths	G/H :1.0/2.0/3.0/4.0/5.0/6.0 Post : 4.0/5.5/7.0	G/H :1.0/2.0/3.0/4.0/5.0 Post : 5.5/7.0	G/H :1.0/1.5/2.0/2.5/3.0/ 3.5/4.0/4.5/5.0 Post: 4.0/5.5/7.0
Surface Treatment	None	Partially TiN coated	Machine or TiN
Sterile	Non-sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K153015, K153521) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter and lengths. Therefore, the subject device is substantially equivalent to the currently cleared devices.		

	Subject Device	Reference Devices	
Part Name	**Angled Abutment**	**Angled Abutment**	**Angled Abutment**
Design			
Applicant	TruAbutment Korea Co., Ltd.	OSSTEM Implant Co., Ltd.	Sewon Medix Inc.
Trade Name	URIS OMNI System	Transfer & Angled Abutment	IH Prosthetic System
510(K) No.	K172100	K153015	K153521
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Pure Titanium Gr.4 (ASTMF67-06)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Transfer & Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or internal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.
Diameters	4.0/ 4.5/5.5mm	4.0mm	4.5/5.0/5.5/6.0mm
Post Angle	17°	17°	15°/25°
Lengths	G/H : 2.0mm~5.0mm Post : 5.5/7mm	G/H : 2.0mm~4.0mm	G/H : 2.0/3.0/4.0 Post : 7.5/8.0
Surface Treatment	None	Partially TiN coated	Machine or TiN
Sterile	Non-sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K153015, K153521) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter and lengths. Therefore, the subject device is substantially equivalent to the currently cleared devices.		

	Subject Device	Reference Devices	
Part Name	**Milling Abutment**	**FreeForm ST Abutment**	**FreeMilling Abutment**
Design			
Applicant	TruAbutment Korea Co., Ltd.	OSSTEM Implant Co., Ltd.	Sewon Medix Inc.
Trade Name	URIS OMNI System	OSSTEM Implant System - Abutment	IH Prosthetic System
510(K) No.	K172100	K161689	K153521
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Pure Titanium Gr.4 (ASTMF67-06)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or internal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.
Diameters	4.0/5.0/6.0/7.0mm	4.0, 5.0, 5.5, 6.0, 7.0mm	4.5/5.0/5.5/6.0mm
Lengths	13.9/14.1/14.85mm	14, 14.5, 14.6mm	G/H : 1.0/2.0/3.0mm Post : 10/11/12mm
Surface Treatment	None	Partially TiN coated	Machine or TiN
Sterile	Non-sterile	Non-sterile	Non-sterile
Milled by hand	Yes	Yes	Yes
No Angular correction	Straight only	N/A	N/A
SE	The subject device and reference devices (K161689, K153521) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter and lengths. Therefore, the subject device is substantially equivalent to the currently cleared devices.		

	Subject Device	Reference Devices
Part Name	**Temporary Abutment**	**RC Temporary Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd.	Straumann USA
Trade Name	URIS OMNI System	Straumann RC Temporary Abutments
510(K) No.	K172100	K093027
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Titanium alloy (TAN)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The Straumann RC Temporary Abutments are indicated for use in Straumann RO Bone Level Implants for temporary restorations of single crowns and bridges for up to six months.
Diameters	3.7 / 4.3mm	4.5mm
Lengths	Height 10mm	Height 11mm
Surface Treatment	None	None
Maximum Duration	Less than 6 months	Less than 6 months
Sterile	Non-sterile	Non-sterile
SE	The subject temporary abutment and reference devices are substantially equivalent in intended use, material, surface treatment, design, dimension and maximum duration of 6 months. K093027 is selected as a reference device as it is indicated for temporary restorations of single crowns and bridges for up to six months. The diameters of the subject device are slightly different from the Reference devices. However, the diameter of 4.3mm is in the range of diameters of predicates and this dimensional difference doesn't affect substantial equivalence.	

	Subject Device	Reference Device
Part Name	**Abutment Screw**	**Abutment Screw**
Design		
Applicant	TruAbutment Korea Co., Ltd.	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI System	OSSTEM Implant System - Abutment
510(K) No.	K172100	K161689
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Indications For Use/ Intended Use	URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	1.9/2.3mm	2.0, 2.05, 2.2, 2.3, 2.5mm
Lengths	7.2/7.7mm	3.35, 5.6, 7.5, 8.35, 9.6, 10.2mm
Surface Treatment	None	N/A
Sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K161689) have the same intended use, have similar technological characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter and lengths. Therefore, the subject device is substantially equivalent to the currently cleared devices.	

URIS Fixture has same material, dimensions and indication for use and similar surface treatment, machining/manufacturing, design and technological characteristics as the predicate devices. URIS Prosthetic System has same indication for use and similar manufacturing process including raw material, machining, dimensions, angulation, and surface treatment and similar design and technological characteristics as the predicate devices.
The differences between the subject device and predicate devices are detailed shape and detailed dimension of diameter and length.
Any differences between the subject device and predicate devices do not raise new types of substantially equivalent issues.

Non-Clinical Test Data

The following tests were performed for the subject device:

- Bacterial Endotoxin Testing (LAL) in accordance with USP <85> and USP <161>
- Biocompatibility Testing such as cytotoxicity according to ISO 10993-5:2009, irritation according to ISO 10993-10:2010, sensitization according to ISO 10993-10:2010, systemic toxicity according to ISO 10993-11:2006, genotoxicity according to ISO 10993-3:2014, and implantation according to ISO 10993-6:2007.
- Sterilization Testing according to ISO 11137-1,-2,-3 and ISO 11737-1,-2
- End user sterilization Testing according to ISO 17665-1,-2
- Shelf Life Testing according to ISO 11607-1,-2 / ASTM F1980-07, ASTM F88, ASTM F1140, ASTM F1929, ASTM F2096 and sterility testing.
- Fatigue Testing according to ISO 14801:2016
- SEM (Scanning electron microscopy) images and EDS (Energy Dispersive X-ray Spectroscopy) analysis

Biocompatibility testing has been completed. Requirements for biological evaluation of the subject device were based on the ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
Fatigue testing was conducted according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” and ISO 14801:2016 Dentistry - Fatigue test for endosseous dental implants under the worst-case scenario.

The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device.

No clinical data were included in this submission.

Conclusions

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