October 7, 2020

TruAbutment Inc.
Chris Choi
Director
17742 Cowan
Irvine, California 92614

Re: K200817
Trade/Device Name: URIS OMNI Narrow System & Prosthetic
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 5, 2020
Received: September 8, 2020

Dear Chris Choi:

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,

for

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200817

Device Name
URIS OMNI Narrow System & Prosthetic

Indications for Use *(Describe)*
URIS OMNI Narrow System is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, 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 URIS OMNI Prosthetic abutments are intended for use with URIS OMNI dental implants to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

All digitally designed abutments and/or coping for use with URIS OMNI Prosthetic abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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

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

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

510(k) Summary

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

Submitter:

TruAbutment Inc.
Eunjin Jang
17742 Cowan,
Irvine CA 92614 USA
Email: eunjin.jang@truabutment.com

Phone: 1-714-956-1488

Official Correspondent

TruAbutment Inc.
Chris Choi
17742 Cowan,
Irvine CA 92614 USA
Email: chris.choi@truabutment.com
Phone: 1-714-956-1488

Device Information:

Device Name: URIS OMNI Narrow System & Prosthetic
Classification Name: Endosseous Dental Implant
Classification: Class II
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation number: 21 CFR 872.3640
Date Prepared: 10/06/2020

Predicate Device

- Primary Predicate Device:
  - URIS OMNI System (K172100) by TruAbutment Korea Co., Ltd.
- Reference Devices:
  - Nobel Active 3.0 (K102436) by Nobel Biocare.
  - OSSTEM Implant System (K161689) by Osstem Implant Co., Ltd .
  - Hiossen Prosthetic System (K140507) by Osstem Implant Co., Ltd .
  - Osstem Abutment System (K182091) by Osstem Implant Co., Ltd .
  - Multi Angled Abutment (K123755) by Osstem Implant Co., Ltd .
  - SMART builder System (K120951) by Osstem Implant Co., Ltd.
  - AnyOne Internal Implant System (K123988) by Megagen Implant Co., Ltd.
  - ET US SS Prosthetic System (K160670) by Osstem Implant Co., Ltd.
  - Preat Abutments (K183518) by Preat Corporation.
  - Oneplant Dental Implant System (K081748) by WARANTEC Implant Co., Ltd.
  - InCoris Zi (K123664) by Sirona Dental Systems GmbH.
  - RelyX Unicem 2Automix (K100756) by 3M ESPE
  - TruAbutment DS (K183106) by TruAbutment Korea Co., Ltd.

Device Description

URIS OMNI Narrow System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI Straight 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 Straight implant has straight wall with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have Narrow (Ø 3.15 mm) platform sizes. Both implant lines share the following diameters and lengths.

Ø 3.15 x 10, 11.5, 13, 14.5mm (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 Ball Abutment, Retainer Cap, Retainer, T LOC Straight Abutment, T Loc Titanium Cap, Multi-Unit Straight Abutment, Multi-Unit Angled Abutment, Multi-Unit Healing Cap, Multi-Unit Ti Cylinder, Multi-unit temporary cylinder, Multi-Unit Base, Multi-Unit Cylinder screw, URIS DS, URIS Base. No additional angulation is to be included in the when using a coping or cylinder (i.e., Multi-unit Ti Cylinder, Multi-unit Temporary Cylinder, Multi-unit Base) with any of the Multi-unit Abutments.

Cover screw and healing abutment are anodized in yellow or green.

Device Component	Diameters (Ø)	Lengths	Angulation
OMNI Straight Fixture	3.15mm	10~14.5mm	
OMNI Tapered Fixture	3.15mm	10~14.5mm	
Ball Abutment	3.5mm	Cuff Height: 1.0~6.0mm	
Retainer Cap	5.1mm	3.9mm	
Retainer	5.1mm	2.1mm	
T LOC Straight Abutment	3.8mm	Cuff Height: 1.0~6.0mm	
T LOC Titanium Cap	5.4mm	2.3mm	
Multi-Unit Straight Abutment	5.0mm	Cuff Height: 1.0mm~6.0mm	
Multi-Unit Angled Abutment		Cuff Height: 3.0mm~5.0mm	17°
		Cuff Height: 4.0mm~6.0mm	29.5°
Multi-Unit Healing Cap	5.1mm	4.5mm	
Multi-Unit Ti Cylinder	5.0mm	5.0mm	
Multi-unit temporary cylinder	5.0mm	12mm	
Multi-Unit Base	5.0mm	4.35/7.35mm	
Multi-unit cylinder screw	1.6mm	3.3mm	
URIS DS	Ø3.8~ Ø 5.5mm	6~11mm	0~25°
URIS Base – Titanium Base Component	4.0mm/4.3mm	Cuff Height: 1.0/2.0mm Post Height : 3.5/5.5mm	

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.

URIS Base consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment. URIS Base is made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. It is compatible with the following systems:

Dental Implants

- URIS OMNI System Implants (K172100) 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm
- URIS OMNI Narrow System Implants (Proposed) 3.15 mm

Raw material blanks

- InCoris Zi (ZrO2) by Sirona Dental Systems GmbH, L size blanks, cleared under K123664.

Cement

- RelyX Unicem 2Automix by 3M ESPE, cleared under K100756.

All zirconia superstructure that composes the final abutment must be designed and milled through the 3 shape CAD/CAM System, by TruAbutment validated milling center, according to the prosthetic planning and patient clinical situation. The superstructure is cemented to the TruBase S in the lab. Use "RelyX Unicem 2Automix" as an adhesive extraorally to connect.

URIS Base is provided non-sterile therefore must be sterilized after the cementation of the zirconia superstructure on the URIS Base.

Design Limitation for Zirconia superstructure

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~15°
Minimum and Maximum Cuff Height	0.5~5 mm
Minimum and Maximum diameter at abutment/implant interface	∅5.0mm~∅8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm

URIS DS abutment as a patient matched titanium abutment compatible with both URIS OMNI System (K172100) and URIS OMNI Narrow System (subject).

Design Limitation for URIS DS

Design parameter	Subject System (K200817) Design Limit	URIS OMNI System (K172100) Design Limit
Minimum and Maximum Gingival Height	0.5~4mm	0.5~4mm
Minimum and Maximum diameter at abutment/implant interface	∅3.8~∅5.5	∅3.8~∅5.5
Minimum and Maximum length of abutment	6~11mm	6~11mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~8mm	4~8mm
Minimum wall thickness at abutment/implant interface	0.4mm	0.4mm
Minimum and Maximum abutment angle	0~25º	0~25º

Indication for Use

URIS OMNI Narrow System is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, 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 URIS OMNI Prosthetic abutments are intended for use with URIS OMNI dental implants to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

All digitally designed abutments and/or coping for use with URIS OMNI Prosthetic abutments are intended to be sent to a TruAbutment-validated milling center for manufacture

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	K200817	K172100	K102436
Device Name	URIS OMNI Narrow System & Prosthetic	URIS OMNI System	Nobel Active 3.0
Manufacturer	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd	Nobel Biocare
Indication for Use	URIS OMNI Narrow System is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, 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 URIS OMNI Prosthetic abutments are intended for use with URIS OMNI dental implants to provide support for prosthetic restorations such as crowns, bridges, or over-dentures. All digitally designed abutments and/or coping for use with URIS OMNI Prosthetic abutments are intended to be sent to a TruAbutment-validated milling center for manufacture	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 NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth,in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.
Design			

	Subject Device	Primary Predicate Device	Reference Devices
Structure	- Internal Hex- connected - Submerged Fixture	- Internal Hex- connected - Submerged Fixture	-Internal Hex - Bone Level Implant
Body Diameter (D)	3.15mm	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm	3.0mm
Length (mm)	10, 11.5, 13, 14.5mm	7, 8.5, 10, 11.5, 13, 14.5mm	10, 11.5, 13, 15mm
Material of Fixture	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)	TiUnite
Sterilization	Gamma Sterilization	Gamma Sterilization	Radiation Sterile
Shelf Life	5years	5years	N/A
Implant Body Features	Threaded	Threaded	Threaded
Product Code	DZE	DZE	DZE
SE	The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices. The Indications for Use Statement (IFUS) for subject device abutment is substantially equivalent in intended use to the primary predicate device K172100, and the reference devices K102436. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The minor differences between the IFUS for the subject device and the primary predicate include: the subject device IFUS includes the term “URIS OMNI Narrow System & Prosthetic is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors” and the primary predicate IFUS does not. The other minor differences are related to the specific device names, validated milling centers, and the compatible OEM implant lines. None of these minor differences impact substantial equivalence because both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.		

URIS Abutments

	Subject Device	Predicate Devices
Part Name	**Ball Abutment**	**Stud Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd	Osstem Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	OSSTEM Implant System
510(K) No.	K200817	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)
Indication For Use/ Intended Use	Ball Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit cement retained restorations	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	3.5mm	3.5mm
Lengths	G/H : 1.0/2.0/3.0/4.0/5.0/6.0mm	6.0/6.4/7.0/7.4/8.0/8.4/9.0/9.4/10/10.4/11 /11.4mm
Surface Treatment	None	Partial TiN coated in upper
Sterile	Non-sterile	Non-sterile
SE	The following subject device (Ball Abutment) is substantially equivalent to the predicate device (Stud Abutment, K161689). The subject device and the predicate device K161689 have internal implant interface connections, and are made of Ti-6Al-4V ELI. The minor differences between the IFUS for the subject device and the predicate is surface treatment. The subject device doesn't include surface treatment. The predicate device includes partial TiN coasted in upper.	

	Subject Device	Predicate Devices
Part Name	**Retainer Cap**	**O-ring Retainer Cap**
Design		
Applicant	TruAbutment Korea Co., Ltd	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	OSSTEM Implant System
510(K) No.	K200817	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)	Titanium Gr. 3 (ASTM F67)
Indication For Use/ Intended Use	Retainer Cap is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	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	5.1mm	5.0mm
Lengths	3.9mm	3.9mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and predicate 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.	

	Subject Device	Predicate Devices
Part Name	**Retainer**	**Retainer**
Design		
Applicant	TruAbutment Korea Co., Ltd	OSSTEM Implant Co., Ltd
Trade Name	URIS OMNI Narrow System & Prosthetic	Hiossen Prosthetic System
510(K) No.	K200817	K140507
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
Indication For Use/ Intended Use	Retainer is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	Use for marking stud-type over denture Hiossen Prosthetic system is intended for use with a dental implant fixture to provide support for prosthetic restoration such as crowns, bridges, or over-dentures
Diameters	5.1mm	5.0mm
Lengths	3.9mm	2.0mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and predicate devices (K140507) 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	Predicate Devices
Part Name	**T LOC Straight Abutment**	**Port Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd.	OSSTEM Implant Co., Ltd
Trade Name	URIS OMNI Narrow System & Prosthetic	Osstem Abutment System
510(K) No.	K200817	K182091
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(ASTM F136)
Indication For Use/ Intended Use	T LOC Straight Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit cement retained restorations.	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	3.8mm	3.5~5.1mm
Lengths	G/H : 1.0/2.0/3.0/4.0/5.0/6.0 mm	G/H:1.0 ~ 7.0 mm
Surface Treatment	None	Partial TiN coated in upper
Sterile	Non-sterile	Non-sterile
SE	The subject device (T LOC Straight Abutment) is substantially equivalent to the predicate device (Port Abutment, K182091). The subject device and the predicate device K182091 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the IFUS for the subject device and the predicate is surface treatment. The subject device doesn't include surface treatment. The predicate device includes partial TiN coasted in upper.	

	Subject Device	Predicate Devices
Part Name	**T LOC Titanium Cap**	**Port Male Cap**
Design		
Applicant	TruAbutment Korea Co., Ltd	Osstem Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	Osstem Abutment System
510(K) No.	K200817	K182091
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)
Indication For Use/ Intended Use	T LOC Titanium Cap is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	5.4mm	5.5mm
Lengths	2.3mm	2.25mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and predicate devices (K182091) 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	Predicate Devices
Part Name	**Multi-unit Straight Abutment**	**Multi Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd.	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	OSSTEM Implant System
510(K) No.	K200817	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)	Titanium Alloy (Ti-6Al-4V)
Indication For Use/ Intended Use	Multi-Unit Straight Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit cement retained restorations.	Using for edentulous mandible or maxilla. Usually use to make full denture Screw Retained Restoration
Diameters	5.0mm	4.8mm
Lengths	G/H :1.0/2.0/3.0/4.0/5.0/6.0mm	8.3,8.7, 9.3, 9.7, 10.3, 10.7, 11.3, 11.7, 12.3, 12.7mm
Surface Treatment	None	TiN coating
Sterile	Non-sterile	Non-sterile
SE	The subject device (Multi-unit Straight Abutment) is substantially equivalent to the predicate device (Multi Abutment, K161689). The subject device and the predicate device K161689 have internal implant interface connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the subject device and the predicate is surface treatment. The subject device doesn't include surface treatment. The predicate device includes partial TiN coasted in upper.	

	Subject Device	Predicate Devices
Part Name	**Multi-unit Angled Abutment**	**Multi Angled Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	Multi Angled Abutment
510(K) No.	K200817	K123755
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)
Indication For Use/ Intended Use	Multi-Unit Angled Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit cement retained restorations.	Multi Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	5.0mm	4.8mm
Lengths	G/H : 3.0/4.0/5.0(17°) G/H : 4.0/5.0/6.0(29.5°)	3.17, 3.4, 4.17, 4.4, 4.76, 4.86, 5.17, 5.4, 5.76, 5.86, 6.76, 6.86 (17°) 3.17, 3.4, 4.17, 4.4, 4.76, 4.86, 5.17, 5.4, 5.76, 5.86, 6.76, 6.86 (30°)
Post Angle	17° / 29.5°	17° / 30°
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (Multi-unit Angled Abutment) are substantially equivalent to the predicate device (Multi Angled Abutment, K123755). The subject device and the predicate device K123755 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the subject device and the predicate is angulation. The subject device is for multiple-unit restorations, include angulations up to 29.5°. The predicate device is for multiple-unit restorations, include angulations up to 30°	

	Subject Device	Predicate Devices
Part Name	**Multi-unit Healing Cap**	**Healing Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd	Osstem Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	SMART builder System
510(K) No.	K200817	K120951
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)	Pure TitaniumGrade4 (ASTMF67)
Indication For Use/ Intended Use	The Multi-unit healing cap is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	SMART builder is a metaldevice intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.
Diameters	5.1mm	4.0~7.0
Lengths	4.5mm	3.35~4.22
Surface Treatment	None	None
Sterile	Non-sterile	Gamma Sterilization
SE	The subject device and predicate devices (K120951) 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	Predicate Devices
Part Name	**Multi-unit Ti Cylinder**	**Multi-unit EZ Post Cylinder**
Design		
Applicant	TruAbutment Korea Co., Ltd	Megagen Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	AnyOne Internal Implant System
510(K) No.	K200817	K123988
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)	CP4 Titanium and Ti-6A1-4V-ELI
Indication For Use/ Intended Use	Multi-unit Ti Cylinder is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.	The AnyOne TM Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Diameters	5.0mm	Hex/Non-Hex: 5.0mm
Lengths	5.0mm	Not stated in 510(k) summary
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and Predicate devices (K123988) 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	Predicate Devices
Part Name	**Multi-unit Temporary Cylinder**	**RC Temporary Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd	OSSTEM Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	ET US SS Prosthetic System
510(K) No.	K200817	K160670
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 (ASTM F 67)
Indication For Use/ Intended Use	Multi-unit Temporary Cylinder is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.	Esthetic-low Temporary Cylinder is used for prosthetic restoration. This is used to make temporary prosthesis and designed to minimized indication constraints.
Diameters	5.0mm	4.8/5.5mm
Lengths	12mm	12mm
Surface Treatment	None	Not stated in 510(k) summary
Maximum Duration	Less than 6 months	Less than 6 months
Sterile	Non-sterile	Non-sterile
SE	The subject temporary abutment and Predicate devices are substantially equivalent in intended use, material, surface treatment, design, dimension and maximum duration of 6 months. K160670 is selected as a predicate 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 4.8, 5.5mm is in the range of diameters of predicates and this dimensional difference doesn't affect substantial equivalence.	

	Subject Device	Predicate Devices
Part Name	**Multi-unit Base**	**Multi-unit Cylinder**
Design		
Applicant	TruAbutment Korea Co., Ltd	WARANTEC Implant Co., Ltd.
Trade Name	URIS OMNI Narrow System & Prosthetic	Oneplant Dental Implant System
510(K) No.	K200817	K081748
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
Indication For Use/ Intended Use	Multi-unit Base is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.	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, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.
Diameters	5.0mm	Hex/Non-Hex: 4.5/5.5mm
Lengths	4.35/7.35mm	Not stated in 510(k) summary
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and predicate devices (K081748) 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	Predicate Device
Part Name	**Multi-unit Cylinder Screw**	**EbonyGold Cylinder Screw**
Design		
Applicant	TruAbutment Korea Co., Ltd	OSSTEM Implant Co., Ltd
Trade Name	URIS OMNI Narrow System & Prosthetic	Osstem Abutment System
510(K) No.	K200817	K182091
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 Ti-6Al-4V (ASTM F136)
Indication For Use/ Intended Use	Multi-unit Cylinder Screw is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Diameters	1.6mm	2.2/2.5 mm
Lengths	3.3mm	4.35/ 4.9 mm
Surface Treatment	None	N/A
Sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K182091) 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	Predicate Devices
Part Name	**URIS DS**	**TruAbutment DS**
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS OMNI Narrow System & Prosthetic	TruAbutment DS
510(K) No.	K200817	K183106
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-6AI-4V ELI
Indication For Use/ Intended Use	URIS DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems: • URIS OMNI System Implants (K172100) 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm • URIS OMNI Narrow System Implants (Proposed) 3.15 mm All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.	The TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems: •Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm •BioHorizons Laser-Lok Implant System (K093321) 3.0 mm The available range of diameters is summarized below: Tapered Internal / Laser-Lok 3.0 Implant Ø (mm) : 3.0 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex Tapered Internal Implant Ø (mm) : 3.4 / Implant Platform (mm) : 3.0 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 3.8 / Implant Platform (mm) : 3.5 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 4.6 / Implant Platform (mm) : 4.5 / Type of Implant-Abutment Connection : Internal Hex Implant Ø (mm) : 5.8 / Implant Platform (mm) : 5.7 / Type of Implant-Abutment Connection : Internal Hex All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for

	Subject Device	Predicate Devices
Part Name	**URIS DS**	**TruAbutment DS**
		manufacture.
CAD Design Limits	Minimum and Maximum Gingiva Height: 0.5~4mm Minimum and Maximum diameter at abutment/implant interface: ∅3.8~∅5.5 Minimum and Maximum length of abutment: 6~11mm Minimum and Maximum length of abutment post (length above the abutment collar/gingival height): 4~8mm Minimum wall thickness at abutment/implant interface: 0.4mm Minimum and Maximum abutment angle: 0~25º	Minimum and Maximum Gingiva Height: 0.5~4mm Minimum and Maximum diameter at abutment/implant interface: ∅3.8~∅5.5 Minimum and Maximum length of abutment: 6~11mm Minimum and Maximum length of abutment post (length above the abutment collar/gingival height): 4~8mm Minimum wall thickness at abutment/implant interface: 0.4mm Minimum and Maximum abutment angle: 0~25º
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (URIS DS) are substantially equivalent to the predicate device (TruAbutment DS, K183106). The subject device and the predicate device K183106 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization and are same CAD Design Limits. The minor differences between the IFUS for the subject device and the primary predicate is compatible system. The subject device is compatible with URIS OMNI System Implants and URIS OMNI Narrow System.	

	Subject Device	Predicate Devices
Part Name	**URIS Base**	**Titanium Base**
Design		
Applicant	TruAbutment Korea Co., Ltd.	Preat Corporation
Trade Name	URIS OMNI Narrow System & Prosthetic	Preat Abutments
510(K) No.	K200817	K183518
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) Zirconia Oxide	Ti-6Al-4V alloy Zirconia Oxide
Indication For Use/ Intended Use	URIS Base is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations. All digitally designed zirconia superstructures for use with the URIS Base are intended to be sent to a TruAbutment-validated milling center for manufacture.	Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of the major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment, All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit
Abutment /Implant Platform Diameter (mm)	Narrow 2.6 Regular 3.3	3.0 – 6.5
Design parameters of zirconia superstructures	Maximum Angulation 15° Maximum Cuff Height 5mm Minimum Diameter Ø 5.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm	Minimum wall thickness-0.5mm; Minimum post height for single-unit restorations-4.0mm; Maximum gingival height-5.0mm; and All zirconia superstructures are for straight abutments only.
Abutment	Internal connection	Internal connection

	Subject Device	Predicate Devices
Part Name	**URIS Base**	**Titanium Base**
/Implant Interface		
Sterile	Non-sterile	Non-sterile
SE	The subject device (URIS Base) are substantially equivalent to the predicate device (Titanium Base, K183518). The subject device and the predicate device K183518 have internal implant interface connections, same prosthesis attachment, restoration, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the subject device and the predicate is design parameters for abutment/implant platform diameter and zirconia superstructures. The predicate device are for straight abutments only, while the subject device can compensate for angles up to 15°.	

Substantial equivalence summary

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The Indications for Use Statement (IFUS) for subject device abutment is substantially equivalent in intended use to the primary predicate device K172100, and the reference devices K102436. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The minor differences between the IFUS for the subject device and the primary predicate include:
the subject device IFUS includes the term “URIS OMNI Narrow System & Prosthetic is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors.” and the primary predicate IFUS does not.
The other minor differences are related to the specific device names, validated milling centers, and the compatible OEM implant lines. None of these minor differences impact substantial equivalence because both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The following subject device (Ball Abutment) is substantially equivalent to the predicate device (Stud Abutment, K161689). The subject device and the predicate device K161689 have internal implant interface connections, and are made of Ti-6Al-4V ELI. The minor differences between the IFUS for the subject device and the predicate is surface treatment. The subject device doesn't include surface treatment. The predicate device includes partial TiN coasted in upper.

The subject device (T LOC Straight Abutment) is substantially equivalent to the predicate device (Port Abutment, K182091). The subject device and the predicate device K182091 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the IFUS for the subject device and the predicate is surface treatment. The subject device doesn't include surface treatment. The predicate device includes partial TiN coasted in upper.

The subject device (Multi-unit Straight Abutment) is substantially equivalent to the predicate device (Multi Abutment, K161689). The subject device and the predicate device K161689 have internal

implant interface connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the IFUS for the subject device and the predicate is surface treatment. The subject device doesn't include surface treatment. and abutment with a post length of less than 4mm is only available for multi-unit cases. The predicate device includes partial TiN coasted in upper.

The subject device (Multi-unit Angled Abutment) are substantially equivalent to the predicate device (Multi Angled Abutment, K123755). The subject device and the predicate device K123755 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the IFUS for the subject device and the predicate is angulation. The subject device is for multiple-unit restorations, include angulations up to 29.5°. and abutment with a post length of less than 4mm is only available for multi-unit cases. The predicate device is for multiple-unit restorations, include angulations up to 30°

The subject device (URIS DS) are substantially equivalent to the predicate device (TruAbutment DS, K183106). The subject device and the predicate device K183106 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization and are same CAD Design Limits. The minor differences between the IFUS for the subject device and the primary predicate is compatible system. The subject device is compatible with URIS OMNI System Implants and URIS OMNI Narrow System. and abutment with a post length of less than 4mm is only available for multi-unit cases. The predicate device is compatible with BioHorizons Laser-Lok Implant System.

The subject device (URIS Base) are substantially equivalent to the predicate device (Titanium Base, K183518). The subject device and the predicate device K183518 have internal implant interface connections, same prosthesis attachment, restoration, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. The minor differences between the subject device and the predicate is design parameters for abutment/implant platform diameter and zirconia superstructures. The predicate device are for straight abutments only, while the subject device can compensate for angles up to 15°. Other than the devices mentioned (Retainer, Retainer Cap, T Loc titanium Cap, Multi-unit Healing Cap, Multi-unit Ti Cylinder, Multi-unit Temporary Cylinder, Multi-unit Base, Multi-unit Cylinder screw) 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.

Non-Clinical Test Data

The following tests were performed:

- Bacterial Endotoxin Testing (LAL) in accordance with USP <85> and USP <161>
- Biocompatibility Testing according to ISO 10993-1.
- 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 Narrow System & URIS Prosthetic System is substantially equivalent to predicate devices as described herein.