December 29, 2023

TruAbutment Inc.
Chris Kim
Manager
17666 Fitch
Irvine, California 92614

Re: K230438
Trade/Device Name: URIS Smart Path Implant System & Prosthetic
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 5, 2023
Received: December 1, 2023

Dear Chris Kim:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230438

Device Name
URIS Smart Path Implant System & Prosthetic

Indications for Use *(Describe)*
URIS Smart Path Implant System & Prosthetic 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.
All digitally designed abutments and/or coping for use with URIS Smart Path Prosthetic abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.

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
K230438

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Device Information

- Trade Name: URIS Smart Path Implant System & Prosthetic
- Common Name: Dental implants
- Classification Name: Endosseous Dental Implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date prepared: 12/29/2023

Predicate Devices/ Reference Devices:

The subject device is substantially equivalent to the following predicate and refernce devices:

Primary Predicate:

- URIS OMNI System (K172100) by TruAbutment Korea Co., Ltd.

Reference Devices:

- IBS System (K220517) by InnoBioSurg Co., Ltd.
- URIS OMNI Narrow System & Prosthetic (K200817) by TruAbutment Korea Co., Ltd.
- InCoris Zi (K123664) by Sirona Dental Systems GmbH.
- RelyX Unicem 2Automix (K100756) by 3M ESPE

General Description

URIS Smart Path Implant 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 treated is SLA (Sandblasted, Large grit and Acid etched) and is provided sterile. It consists of two implant lines, the Smart Path OMNI Thread and the Smart Path extra aggressive Thread, with corresponding cover screws, healing abutments and prosthetic abutments. The Smart Path implant has a tapered wall with a single thread design. The Smart Path extra aggressive Thread is straight walled with smaller threading at the coronal end, and bigger threading at the apical end.

URIS SP Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of SP Healing Abutment, SP Temporary Abutment, SP Multi-Unit Straight Abutment, SP Multi-Unit Angled Abutment, SP T-L Straight Abutment, URIS SP Base, URIS SP DS, SP Abutment Screw.
Cover screw and healing abutment are anodized in yellow or green or purple.

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 SP 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:

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.

Design Limitation for Zirconia superstructure

Design parameter	Limit (Min.~Max.)
Maximum Angulation	0~15°
Maximum Cuff Height	0.5~5.0 mm
Minimum Diameter	Ø5.0~ Ø8.0
Minimum wall thickness at abutment/implant interface	0.4mm
Minimum and Maximum length of abutment post	4.0 ~6.0 mm

Indication for Use

URIS Smart Path Implant System & Prosthetic 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.
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 SP Fixture

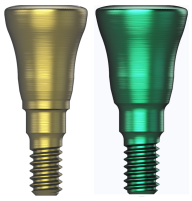
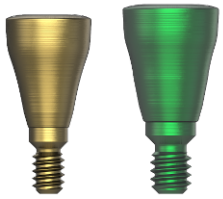
	Subject Device	**Predicate Device**	**Reference Devices**
510K Number	K230438	K172100	K220517
Device Name	URIS Smart Path Implant System & Prosthetic	URIS OMNI System	IBS System
Manufacturer	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd	InnoBioSurg Co., Ltd.
Indications for Use	URIS Smart Path Implant System & Prosthetic 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. 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	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 IBS System is intended to replace missing teeth to restore chewing function. The IBS System can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.

	Subject Device	Predicate Device	Reference Devices
510K Number	K230438	K172100	K220517
	manufacture.		
Design			
Structure	- Internal - connected - Submerged Fixture	- Internal Hex- connected - Submerged Fixture	- Internal Hex- connected - Non Submerged Fixture
Body Diameter (D) and Length (mm)	**SP OMNI Thread** Ø3.5 x 8.5, 10, 11.5, 13, 14.5mm, Ø4.0 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø5.0 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø5.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø6.0 x 7, 8.5, 10mm, Ø6.5 x 7, 8.5, 10mm **SP Extra Aggressive Thread** Ø3.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø5.5 x 7, 8.5, 10mm,	Ø3.5 x 8.5, 10, 11.5, 13, 14.5mm, Ø4.0 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø5.0 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø5.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø6.0 x 7, 8.5, 10mm, Ø6.5 x 7, 8.5, 10mm	Ø7.0 x 7, 8, 9, 10, 11, 12, 13mm Ø7.5 x 7, 8, 9, 10, 11, 12, 13mm Ø8.0 x 7, 8, 9, 10, 11, 12, 13mm
Material of Fixture	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	Ti-6Al-4V Eli
Surface	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	5years	5years	5years
Implant Body Features	Threaded	Threaded	Threaded
Product Code	DZE	DZE	DZE

	Subject Device	Predicate Device	Reference Devices
510K Number	K230438	K172100	K220517
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 predicate device K172100. 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. Minor differences in the designs, implant connections, dimensions, or sizes between the subject device, the predicate device, and the reference devices do not affect substantial equivalence. The implant body dimension of the subject device is the similar included in K172100. URIS SP Extra Aggressive Implant bodies are only available in limited diameters/lengths. Ø3.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm, Ø5.5 x 7, 8.5, 10mm The subject device and reference device K220517 packaging methods are similar.		

URIS SP Abutments

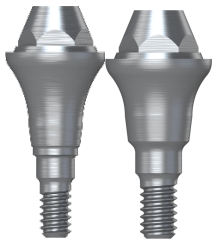
	Subject Device	Predicate Device

Part Name	Healing Abutment	Healing Abutment
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Smart Path Implant System	URIS OMNI System
510(K) No.	K230438	K172100
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)
Description	URIS Smart Path Implant System & Prosthetic 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.	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.
Diameters	4.0/4.5/5.0/6/7mm	4.0/4.5/5.5/6.5/7.5mm
Surface Treatment	Anodizing (Yellow, Green)	Anodizing (Yellow, Green)
Sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K172100) have the similar intended use, have similar technological characteristic, and are made of similar materials. The subject device and reference device have similar physical dimensions, including diameter. Therefore, the subject device is substantially equivalent to the currently cleared devices.	

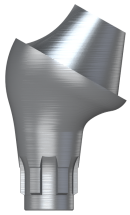
	Subject Device	Reference Device

Part Name	T-L Straight Abutment	T LOC Straight Abutment
Design		
Applicant	TruAbutment Korea Co., Ltd.	TruAbutment Korea Co., Ltd.
Trade Name	URIS Smart Path Implant System	URIS OMNI Narrow System & Prosthetic
510(K) No.	K230438	K200817
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)
Description	T-L 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.	T LOC Straight Abutment 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.
Diameters	3.8mm	3.8mm
Lengths	G/H : 1.0/2.0/3.0/4.0/5.0/6.0 mm	G/H : 1.0/2.0/3.0/4.0/5.0/6.0 mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (T-L Straight Abutment) is substantially equivalent to the predicate device (TLOC Straight Abutment, K200817). The subject device and the predicate device K200817 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization.	

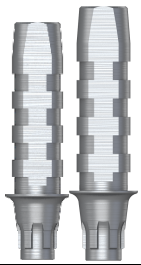
	Subject Device	Reference Device
Part Name	**Multi-Unit Straight Abutment**	**Multi-Unit Straight Abutment**

Design		
Applicant	TruAbutment Korea Co., Ltd.	TruAbutment Korea Co., Ltd.
Trade Name	URIS Smart Path Implant System	URIS OMNI Narrow System & Prosthetic
510(K) No.	K230438	K200817
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)
Description	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.	Multi-Unit Straight Abutment 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.
Diameters	5.0mm	5.0mm
Lengths	G/H :1.0/2.0/3.0/4.0/5.0/6.0mm	G/H :1.0/2.0/3.0/4.0/5.0/6.0mm
Angular correction	No angular correction allowed	No angular correction allowed
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (Multi-unit Straight Abutment) is substantially equivalent to the predicate device (Multi Straight Abutment, K172100). The subject device and the predicate device K172100 have internal implant interface connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization. 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.	

	Subject Device	**Reference Device**

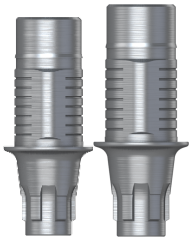
Part Name	Multi-Unit Angled Abutment	Multi-Unit Angled Abutment
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Smart Path Implant System	URIS OMNI Narrow System & Prosthetic
510(K) No.	K230438	K200817
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Description	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-Unit Angled Abutment 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.
Diameters	5.0mm	5.0mm
Lengths	G/H : 3.0/4.0/5.0(17°) G/H : 4.0/5.0/6.0(29.5°)	G/H : 3.0/4.0/5.0(17°) G/H : 4.0/5.0/6.0(29.5°)
Post Angle	17° / 29.5°	17° / 29.5°
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 unit Angled Abutment, K200817). The subject device and the predicate device have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization.	

	Subject Device	Predicate Device

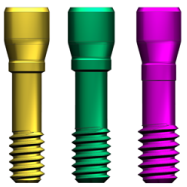
Part Name	Temporary Abutment	Temporary Abutment
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd.
Trade Name	URIS Smart Path Implant System	URIS OMNI System
510(K) No.	K230438	K172100
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Description	URIS Smart Path Implant 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.	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.
Diameters	3.7 / 4.2 / 4.7mm	3.7 / 4.3mm
Lengths	Height 10mm	Height 10mm
Angular correction	Patient-specific customized by hand-milling with no angular correction.	Patient-specific customized by hand-milling with no angular correction.
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. K172100 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 4.7mm is in the range of diameters of predicates and this dimensional difference doesn't affect substantial equivalence.	

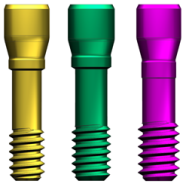
	Subject Device	Reference Device
Part Name	**URIS SP DS**	**URIS DS**
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Smart Path Implant System	URIS OMNI Narrow System & Prosthetic
510(K) No.	K230438	K200817
Classification Name	Endosseous Dental Implant Abutments(872.3630)	Endosseous Dental Implant Abutments(872.3630)
Product Code	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Description	URIS SP 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. All digitally designed abutments and/or coping for use with the URIS SP DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture.	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.
CAD Design Limits	Minimum and Maximum Gingiva Height: 0.5~4mm Minimum and Maximum diameter at abutment/implant interface: Ø3.8~Ø5.5 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 Gingiva Height: 0.5~4mm Minimum and Maximum diameter at abutment/implant interface: Ø3.8~Ø5.5 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 abutment angle: 0~25º
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (URIS SP DS) are substantially equivalent to the reference device (URIS DS, K200817). The subject device and the predicate device K200817 have internal connections, are made of Ti-6Al-4V ELI, and are conducted End User Steam Sterilization and are similar CAD Design Limits.	

	Subject Device	**Reference Device**
Part Name	**URIS Base**	**URIS Base**
Design		
Applicant	TruAbutment Korea Co., Ltd.	TruAbutment Korea Co., Ltd.
Trade Name	URIS Smart Path Implant System	URIS OMNI Narrow System & Prosthetic
510(K) No.	K230438	K200817
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)
Description	URIS SP 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 SP Base are intended to be sent to a TruAbutment-validated milling center for manufacture.	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.
Diameters	3.8mm/4.08mm/4.78mm/4.3mm	4.0mm/4.3mm

	Subject Device	Reference Device
	/4.8mm/5.08mm	
Lengths	Cuff Height: 1.0/2.0/3.0/4.0mm Post Height : 3.5/5.5mm	Cuff Height: 1.0/2.0mm Post Height : 3.5/5.5mm
Design parameters of zirconia superstructures	Min / Max Angulation 15° Min / Max Cuff Height 0.5~5mm Min / Max Diameter Ø5.0~ Ø 8.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm	Min / Max Angulation 15° Min / Max Cuff Height 0.5~5mm Min / Max Diameter Ø5.0~ Ø 8.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (URIS SP Base) are substantially equivalent to the reference device (URIS Base, K200817). The subject device and the reference device K200817 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 diameter and Length. The subject device includes diameter size 3.8mm, 4.08mm, 4.3mm, 4.78mm, 4.8mm , 5.08mm and Length range of 3.5mm to 5.5mm. The predicate device includes diameter size of 4.0mm, 4.3mm and length range of 3.5mm to 5.5mm.	

	Subject Device	Predicate Device
Part Name	**Abutment Screw**	**Abutment Screw**
Design		
Applicant	TruAbutment Korea Co., Ltd.	TruAbutment Korea Co., Ltd.
Trade Name	URIS Smart Path Implant System	URIS OMNI System
510(K) No.	K230438	K172100

	Subject Device	Predicate Device
Part Name	**Abutment Screw**	**Abutment Screw**
Design		
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)
Description	URIS Smart Path Implant System & Prosthetic 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.	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.
Diameters	2.0 / 2.1mm	1.9 / 2.3mm
Lengths	7.7 / 7.9 / 8.2mm	7.2 / 7.7mm
Surface Treatment	Anodizing (Yellow, Green, Purple)	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and predicate device (K172100) have the similar intended use, have similar technological characteristic, and are made of similar materials. The minor differences between the subject device and the predicate is diameter and Length. The subject device includes diameter size 2.0mm, 2.1mm and Length range of 7.7mm to 8.2mm. The predicate device includes diameter size of 1.9mm, 2.3mm and length range of 7.2mm to 7.7mm. The subject device has three color (yellow, green, and purple) anodized treatment on the surface, while the reference device has no surface treatment. It is the similar as the anodizing method of the healing abutment included in K172100. However, those differences don't affect substantial equivalence.	

Subject Device implant bodies has similar material, dimensions and indication for use and similar surface treatment, machining/manufacturing, design and technological characteristics as the predicate and reference devices. URIS SP Prosthetic System has similar 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 and reference devices.

The differences between the subject device and predicate and reference devices are detailed shape and detailed dimension of diameter and length.

Any differences between the subject device and predicate and reference devices do not raise new types of substantially equivalent issues.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic URIS SP Implant system 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, dental 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.

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>
- Sterilization Testing according to ISO 11137-1,-2,-3 and ISO 11737-1,-2
- Shelf Life Testing according to ISO 11607-1,-2 / ASTM F1980-07, ASTM F88, ASTM F1140, ASTM F1929, ASTM F2096 and sterility testing.

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. Biocompatibility testing information is also leveraged from predicate and reference device (K172100 and K200817). The Biocompatibility Test was conducted on the predicate and reference devices is leveraged for the subject device because both products are manufactured with similar materials, manufacturer, manufacturing process.

SEM (Scanning electron microscopy) images and EDS (Energy Dispersive X-ray Spectroscopy) analysis were conducted on the predicate and reference devices is leveraged from our own prior clearance for the identical SLA surface treatment and manufacturing.

Below performance testing and information have been provided for subject implant fixture packaging:

- Human Factors testing (A usability evaluation for aseptic presentation of the subject device, in line with ISO 11607-1:2019 and the recommendations of the FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices.")
- Low and high magnification images at various degrees of rotation following the removal from the packaging (Evaluation of the broken tip at various degrees rotation at a high magnification and low magnification for damage after removal from the packaging and disconnection of the fixture jig)
- Quality System (QS) plan including the method and frequency of acceptance activities to ensure that the devices conform with product specifications with packaging design.

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 Smart Path Implant System & Prosthetic is substantially equivalent to predicate and reference devices as described herein.