July 3, 2025

TruAbutment Inc.
Suna Kim
RA Senior Manager
17666 Fitch
Irvine, California 92614

Re: K243255
Trade/Device Name: URIS Long Implant & Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 29, 2025
Received: May 29, 2025

Dear Suna 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243255

Device Name

URIS Long Implant & Abutments

Indications for Use *(Describe)*

URIS Long Implant & Abutments are 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.

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.
John Kim
17666 Fitch,
Irvine, CA 92614 USA
Email: trura@truabutment.com
Phone: 1-714-7675123

Official Correspondent:
TruAbutment Inc.
Dong uk Shin
17666 Fitch,
Irvine, CA 92614 USA
Email: trura@truabutment.com
Phone: 1-714-7675123

Device Information:
Device Name: URIS Long Implant & Abutments
Classification Name: Endosseous Dental Implant
Classification: Class II
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation number: 21 CFR 872.3640
Date Prepared: 07/02/2025.

Predicate Device

- Primary Predicate Device:
  - URIS OMNI System (K172100) by TruAbutment Korea Co., Ltd.

- Reference Predicate Device:
  - Single Platform SP1 Implant System (K232418) by Southern Implants (Pty) Ltd
  - URIS OMNI Narrow System & Prosthetic (K200817) by TruAbutment Korea Co., Ltd.
  - AOT & T-L Abutment (K231874) by TruAbutment Korea Co., Ltd.

Device Description

General Description

URIS Long Implants 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.
URIS OMNI Long Implants consist of two implant lines, the OMNI Straight and the OMNI Tapered. The OMNI Straight implant features straight walls, with smaller threads at the coronal end and larger threads at the apical end. The OMNI Tapered implant has a tapered wall with a single-thread design.
Both implant lines have two platform sizes, Narrow (Ø 3.5 mm) and Regular (Ø 4.0 – Ø 4.5 mm).
Both implant lines share the following diameters and lengths:

Type		Platform	Diameter (Ø)	Length (mm)
Straight		Narrow	Ø 3.5	16, 18
		Regular	Ø 4.0 – 4.5	16, 18
Tapered		Narrow	Ø 3.5	16, 18
		Regular	Ø 4.0 – 4.5	16, 18

URIS OMNI Long Implants are compatible with the following abutments:

510(K)	Device Component	Diameters (Ø)	Lengths	Angulation
K172100	Cover Screw	2.78 (N) /3.48 (R)	4.875/ 5.375	-
	Healing Abutments	4.0 (N)/ 4.5 (N, R) / 5.5, 6.5, 7.5 (R)	Cuff Height: 1.0 ~ 5.0	-
K200817	Multi-Unit Straight Abutment	5.0 (N, R)	Cuff Height: 1.0 ~ 6.0	-
	Multi-Unit Angled Abutment	5.0 (N, R)	Cuff Height: 3.0 ~ 5.0	17
			Cuff Height: 4.0 ~ 6.0	29.5
	Multi-Unit Healing Cap	5.1 (N, R)	4.5	-
	Multi-Unit Ti Cylinder	5.0 (N, R)	5.0	-
	Multi-Unit Temporary Cylinder	5.0 (N, R)	12	-
	Multi-Unit Base	5.0 (N, R)	4.35/ 7.35	-
	Multi-Unit Cylinder Screw	1.6 (N, R)	3.3	-
K231874	AOT Base	5.3 (N,R)	4.35/ 7.35	-
	AOT Temporary	4.8 (N,R)	12	-
K243255	AOT Straight Abutment	4.8 (N, R)	Cuff Height: 1.0 ~ 6.0	-
	AOT Angled Abutment	4.8 (N, R)	Cuff Height: 3.0 ~ 5.0	17°
			Cuff Height: 4.0 ~ 6.0	30°
	Multi-Unit Base	5.3 (N,R)	4.35 / 7.35	-
	Multi-Unit Base Screw	2.2	4.2	-
	Multi-Unit Temporary Abutment	4.8 (N, R)	12	-
	AOT Direct Screw	2.2	1.35	-
	AOT Plus Direct Screw	2.3	1.56	-
	Multi-Unit Direct Screw	2.2	4.85	-

The abutments are provided non-sterile. All non-sterile products must be sterilized by the end user prior to use.
The AOT Angled Abutment, Multi-Unit Base, and Multi-Unit Temporary Abutment are packaged with their corresponding screw(s).
For convenience, the Multi-Unit Base and Multi-Unit Temporary Abutment are each supplied with two screws included in the package.

The abutments are designed for use with the two implant types submitted in this application. They are also compatible with the implants included in the K172100 URIS OMNI Implant system (Narrow: Ø3.5 mm, lengths 8.5–14.5 mm / Regular: Ø4.0–Ø6.5 mm, lengths 7.0–14.5 mm).

The AOT Straight and AOT Angled Abutments are compatible with the Base and Temporary Abutments included in this submission, as well as those previously cleared under K231874.

Indication for Use

URIS Long Implant & Abutments are 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	K243255	K172100	K232418
Device Name	URIS Long Implant & Abutments	URIS OMNI System	Single Platform SP1 Implant System
Manufacturer	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd	Southern Implants (Pty) Ltd
Indications for Use	URIS Long Implant & Abutments are 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.	The Single Platform SP1 Implant System is intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. The Single Platform SP1 Implant System is intended for immediate function when good primary stability with Appropriate occlusal loading is achieved. The Single Platform SP1 implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
Design			

	Subject Device	Primary Predicate Device	Reference Devices
Structure	- Internal Hex- connected - Submerged Fixture	- Internal Hex- connected - Submerged Fixture	- Internal Cone and Hex
Body Diameter (D)	3.5,-4.0, 4.5 mm	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm	3.50, 4.0 and 5.0mm
Length (mm)	16, 18 mm	7, 8.5, 10, 11.5, 13, 14.5 mm	For Ø3.5implants: 8, 10,11.5, 13, 16, 18, 20 mm For Ø4.0 implants: 8, 10,11.5, 13, 16, 18, 20, 22, 24 mm For Ø5.0 implants: 8, 10, 11.5, 13, 16, 18mm
Material of Fixture	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (coldworked)
Surface	Sand-blasted, large grit, Acid-etched. (S.L.A)	Sand-blasted, large grit, Acid-etched. (S.L.A)	Grit-blasted with a 3.0mm machined section only at coronal end
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	5 years	5 years	10 years
Implant Body Features	Threaded	Threaded	Threaded
Product Code	DZE	DZE	DZE

	Subject Device	Primary Predicate Device	Reference Devices
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. 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 minor difference compared to the predicate device lies in the length. However, this variation does not affect substantial equivalence, as both IFUs clearly state an equivalent intended use to facilitate dental prosthetic restorations and the indications for use are expressed in a substantially similar manner. To support the differences in diameter and length, we have included additional reference devices that are already cleared under 510(k) and cover the range of our subject device. These reference devices demonstrate that the subject device's dimensions fall within the scope of previously cleared implants: K232418: Ø3.5–5.0 mm, Length 16, 18 mm		

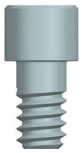
- **URIS Abutments**

	Subject Device	Reference Devices
Part Name	**AOT Straight Abutment**	**Multi-Unit Straight Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd.	TruAbutment Korea Co., Ltd.
Trade Name	URIS Long Implant & Abutments	URIS OMNI Narrow System & Prosthetic
510(K) No.	K243255	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)
Indications 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 only.	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	4.8 mm	5.0 mm
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 (AOT Straight Abutment) is substantially equivalent to the predicate device (Multi-Unit Straight Abutment, K200817). The subject device and the predicate device K200817 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. The diameters of the subject device are slightly different from the predicate devices. However, this dimensional difference doesn’t affect substantial equivalence.	

	Subject Device	Reference Devices
Part Name	**AOT Angled Abutment**	**Multi-Unit Angled Abutment**
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Long Implant & Abutments	URIS OMNI Narrow System & Prosthetic
510(K) No.	K243255	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)
Indications 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 only.	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	4.8 mm	5.0 mm
Lengths	G/H: 3.0/4.0/5.0 (17°) G/H: 4.0/5.0/6.0 (30°)	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 (AOT Angled Abutment) is 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.-The subject device is for single-unit or multiunit restorations, including angulations up to 30°, and abutment with a post length of less than 4 mm is only available for multi-unit cases. The diameters of the subject device are slightly different from the predicate devices. However, this dimension difference was addressed via fatigue testing.	

	Subject Device	Reference Devices
Part Name	**Multi-unit Temporary Abutment**	**Multi-Unit Temporary Cylinder**
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Long Implant & Abutments	URIS OMNI Narrow System & Prosthetic
510(K) No.	K243255	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)
Indications For Use/ Intended Use	Multi-unit Temporary Cylinder is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.	Multi-unit Temporary Cylinder is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.
Diameters	4.8 mm	5.0 mm
Lengths	12 mm	12 mm
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 Predicate devices are substantially equivalent in intended use, material, surface treatment, design, dimension and maximum duration of 6 months. K200817 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 predicate devices. However, this dimensional difference doesn't affect substantial equivalence.	

	Subject Device	Reference Devices
Part Name	**Multi-unit Base**	**Multi-unit Cylinder**
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Long Implant & Abutments	URIS OMNI Narrow System & Prosthetic
510(K) No.	K243255	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)
Indications For Use/ Intended Use	Multi-unit Base is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.	Multi-unit Base is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's chewing function.
Diameters	5.3 mm	5.0 mm
Lengths	4.35/7.35 mm	4.35/7.35 mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and predicate devices (K200817) have the same intended use, have similar technological characteristics, 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	**Multi-Unit Base Screw / AOT Direct Screw/ AOT Plus Screw/ Multi-Unit Direct Screw**	**Multi-unit Cylinder Screw**
Design		
Applicant	TruAbutment Korea Co., Ltd	TruAbutment Korea Co., Ltd
Trade Name	URIS Long Implant & Abutments	URIS OMNI Narrow System & Prosthetic
510(K) No.	K243255	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)
Indications For Use/ Intended Use	AOT Base Screw/AOT Plus Screw/Multi Unit Direct 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.	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.
Diameters	2.2/2.3 mm	1.6 mm
Lengths	4.2/4.5/4.75/4.8/4.85 mm	3.3 mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device and reference devices (K200817) have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter and lengths. The diameters of the subject device are slightly different from the predicate devices. However, this dimensional difference doesn't affect substantial equivalence. The length of the primary predicate device is 3.3mm, while the subject device is 4.2mm, 4.5mm , 4.75mm, and 4.8, 4.85mm.	

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 K200817. 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 minor difference compared to the predicate device lies in the length. However, this variation does not affect substantial equivalence, as the lengths are supported by the K232418 reference device.

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 Long Implant is substantially equivalent to predicate devices as described herein.