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

October 30, 2023

Re: K231874
Trade/Device Name: AOT & T-L Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 29, 2023
Received: October 2, 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)*
K231874

Device Name
AOT & T-L Abutment

Indications for Use *(Describe)*
AOT & T-L Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit restorations.

It is compatible with the following systems:

- Astra OsseoSpeed EV(K130999) 3.0
- Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm
- Dentium Company Limited Implantium (K041368) 3.6, 4.0, 4.5, 5.0 (Regular)
- Implant Direct Legacy2(K192221) 3.0
- Megagen AnyRidge Internal Implant System (K140091) 3.5, 4.0, 4.4, 4.9, 5.4 (3.1)
- Neodent Implant System - GM Helix (K163194, Kl80536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
- Nobel Active 3.0 (K102436) 3.0
- Nobel Active Internal Connection Implant (K071370) NP RP 3.5, 4.3, 5.0
- Nobelactive Wide Platform (Wp) (K133731) WP 5.5
- TS Fixture System (K121995) 3.5 (3.75) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1) mm (Mini, Regular)
- Straumann BLX Implant (Kl73961, Kl81703, K191256) 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB)
- Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (Kl62890) 2.9 (SC)
- Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)
- Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)
- Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.1(3.5), 4.7(4.5), 6.0(5.7)

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
K231874

Submitter
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Device Information

- Trade Name: AOT & T-L Abutment
- Common Name: Endosseous dental implant abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date prepared: 10/30/23

Predicate Devices/ Reference Devices:

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

Primary Predicate:

- URIS OMNI Narrow Implant System (K200817) by TruAbutment Inc.

Reference Devices for OEM Compatibilities:

- Astra OsseoSpeed EV (K120414, K130999) by Astra.
- Dentium Company Limited Implantium (K041368) by Dentium Co., LTD.
- Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts (K192221) by Implant Direct LLC
- Xpeed AnyRidge Internal Implant System (K140091) by Megagen Implant Co., LTD.
- Neodent Implant System – GM Helix (K163194) by Straumann USA, LLC.
- Nobelactive 3.0 (K102436) By Nobel Biocare.
- Nobelactive Internal Connection Implant (K071370) By Nobel Biocare.
- Nobelactive Wide Platform (Wp) (K133731) By Nobel Biocare.
- TS Fixture System (K121995) by Osstem Implant Co., Ltd.

- Straumann BLX Implant System (K173961) by Straumann USA, LLC.
- Straumann BLX Line Extension - Implants (K181703) by Straumann USA, LLC.
- Straumann BLX Ø 3.5 Mm Implants (K191256) by Straumann USA, LLC
- Straumann Ø2.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) by Straumann USA, LLC.
- Straumann® Bone Level Tapered Implants (K140878) by Straumann USA, LLC.
- Zimmer 3.1mmD Dental Implant System (K142082) by Zimmer Dental, Inc.
- Screw Vent® and Tapered Screw Vent® (K013227) by Sulzer Dental Inc.

General Description

AOT & T-L Abutment

AOT & T-L Abutment which are placed into the dental implant to provide support for the prosthetic restoration. The abutments are made of Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136). AOT abutment is a straight multi-unit abutment that connect implant fixtures to a restoration, such as a dental bridge or a denture. AOT products includes abutments and components (AOT Base, AOT Temporary, AOT Base Screw, AOT Plus Screw). T-L abutment is for partial and full arch restorations on endosseous dental implants. AOT & T-L abutments are provided in various gingival cuff height ranging from 1 to 3 mm for AOT , 1 to 6 mm for T-L.

Mechanical resistance of the implant-abutment connection is essential to ensure the correct long-term functional performance of the complete dental restoration. Dimensional compatibility and mechanical performance of bases and screws together with the underlying implant are of primary importance. These concepts are the basis upon which the system design characteristics and functional performance are established.

The AOT & T-L Abutment is a device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.

Indication for Use

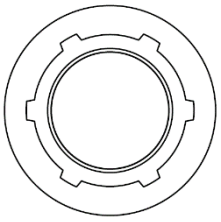
AOT & T-L Abutment

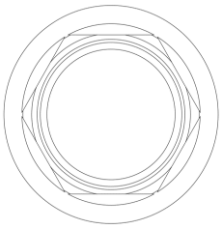
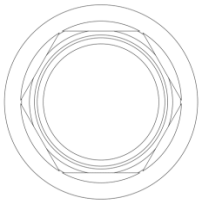
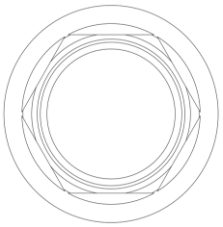
AOT & T-L Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit restorations.

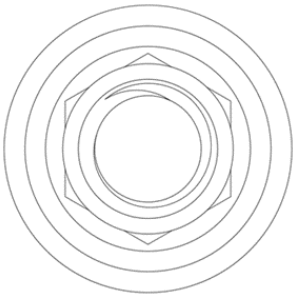
It is compatible with the following systems:

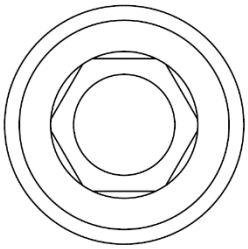
- Astra OsseoSpeed EV(K130999) 3.0
- Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm
- Dentium Company Limited Implantium (K041368): 3.6, 4.0, 4.5, 5.0 (Regular)
- Implant Direct Legacy2(K192221) 3.0
- Megagen AnyRidge Internal Implant System (K140091) 3.5, 4.0, 4.4, 4.9, 5.4 (3.1)
- Neodent Implant System - GM Helix (K163194, Kl80536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
- Nobel Active 3.0 (K102436) 3.0
- Nobel Active Internal Connection Implant (K071370) NP RP 3.5, 4.3, 5.0
- Nobelactive Wide Platform (Wp) (K133731) WP 5.5
- TS Fixture System (K121995) 3.5 (3.75), 4.0 (4.2), 4.5 (4.6) , 5.0 (5.1) mm (Mini, Regular)
- Straumann BLX Implant (Kl73961, Kl81703, K191256) 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB)
- Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (Kl62890) 2.9 (SC)
- Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)
- Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)
- Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.1(3.5), 4.7(4.5), 6.0(5.7)

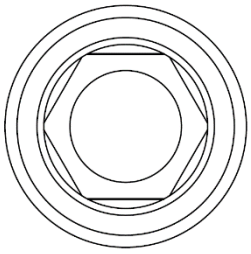
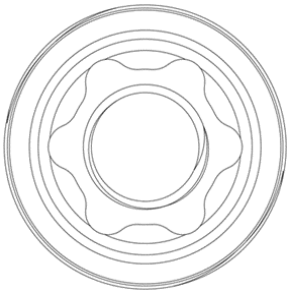
AOT & T-L Abutment are compatible with the following devices:

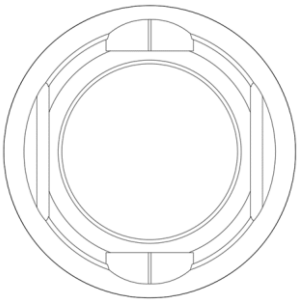
Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
Astra OsseoSpeed EV (K130999)	3.0	8mm	25212	3.0	
		9mm	25213		
		11mm	25214		
		13mm	25215		
		15mm	25216		
Astra OsseoSpeed EV (K120414)	3.6	6mm	25221	3.6	
		8mm	25222		
		9mm	25223		
		11mm	25224		
		13mm	25225		
		15mm	25226		
		17mm	25227		
	4.2	6mm	25231	4.2	
		8mm	25232		
		9mm	25233		
		11mm	25234		
		13mm	25235		
		15mm	25236		
		17mm	25237		
	4.8	6mm	25241	4.8	
		8mm	25242		
		9mm	25243		
		11mm	25244		
		13mm	25245		
		15mm	25246		
		17mm	25247		
	5.4	6mm	25251	5.4	
		8mm	25252		
		9mm	25253		
		11mm	25254		
		13mm	25255		
		15mm	25256		
Dentium SuperLine (K041368)	3.6	8	FX3608SWC	3.6	
		10	FX3610SWC		
		12	FX3612SWC		
		14	FX3614SWC		

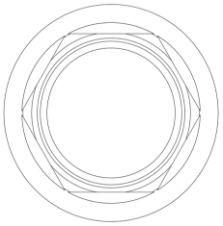
Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
	4.0	8	FX4008SWC	4.0	 Internal Hex
		10	FX4010SWC		
		12	FX4012SWC		
		14	FX4014SWC		
	4.5	8	FX4508SWC	4.5	
		10	FX4510SWC		
		12	FX4512SWC		
		14	FX4514SWC		
	5.0	8	FX5008SWC	5.0	
		10	FX5010SWC		
		12	FX5012SWC		
		14	FX5014SWC		
Implant Direct Legacy (K192221)	3.2	8	823208	3.0	 Internal Hex
		10	823210		
		11.5	823211		
		13	823213		
		16	823216		
Megagen AnyRidge (K140091)	3.5	8	FANIHX3508	3.1	 Internal Hex
		10	FANIHX3510		
		11.5	FANIHX3511		
		13	FANIHX3513		
		15	FANIHX3515		
		18	FANIHX3518		
	4.0	8	FANIHX4008		
		10	FANIHX4010		
		11.5	FANIHX4011		
		13	FANIHX4013		
		15	FANIHX4015		
		18	FANIHX4018		
	4.4	7	FANIHX4508		
		8	FANIHX4508		
		10	FANIHX4510		
		11.5	FANIHX4511		
		13	FANIHX4513		
		15	FANIHX4515		
		18	FANIHX4518		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
	4.9	7	FANIHX5007		
		8	FANIHX5008		
		10	FANIHX5010		
		11.5	FANIHX5011		
		13	FANIHX5013		
		15	FANIHX5015		
		18	FANIHX5018		
	5.4	7	FANIHX5507		
		8	FANIHX5508		
		10	FANIHX5510		
		11.5	FANIHX5511		
		13	FANIHX5513		
		15	FANIHX5515		
		18	FANIHX5518		
Neodent GM (K163194, K180536)	3.5	8	109.943	3.0	 Grand Morse connection
		10	109.944		
		11.5	109.945		
		13	109.946		
		16	109.947		
		18	109.988		
	3.75	8	109.976		
		10	109.977		
		11.5	109.978		
		13	109.979		
		16	109.980		
		18	109.981		
	4.0	8	109.982		
		10	109.983		
		11.5	109.984		
		13	109.985		
		16	109.986		
		18	109.987		
	4.3	8	109.948		
		10	109.949		
		11.5	109.950		
		13	109.951		
		16	109.952		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		18	109.989		
	5.0	8	109.953		
		10	109.954		
		11.5	109.955		
		13	109.956		
		16	109.957		
		18	109.990		
	6.0	8	109.1009		
		10	109.1010		
		11.5	109.1011		
		13	109.1012		
NobelActive (K102436, K071370, K133731)	3.0	10	36769	3.0	 Internal Hex
		11.5	36770		
		13	36771		
		15	36772		
	3.5	10	34125	3.5 (NP)	
		11.5	34126		
		13	34127		
		15	34128		
	4.3	10	34131	3.9 (RP)	
		11.5	34132		
		13	34133		
		15	34134		
	5.0	10	34137	3.9 (RP)	
		11.5	34138		
		13	34139		
		15	34140		
	5.5	10	37808	5.1 (WP)	
		11.5	37809		
		13	37810		
		15	37811		
OSSTEM TS (K121995)	3.5 (3.75)	8.5mm	TS3M3508S	2.1 (Mini)	
		10mm	TS3M3510S		
		11.5mm	TS3M3511S		
		13mm	TS3M3015S		
	4.0 (4.2)	7mm	TS3S4007S	2.5 (Regular)	
		8.5mm	TS3S4008S		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		10mm	TS3S4010S		 Internal Hex
		11.5mm	TS3S4011S		
		13mm	TS3S4013S		
	4.5 (4.6)	7mm	TS3S4507S		
		8.5mm	TS3S4508S		
		10mm	TS3S4510S		
		11.5mm	TS3S4511S		
		13mm	TS3S4513S		
	5.0 (5.1)	7 mm	TS3S5007S		
		8.5 mm	TS3S5008S		
		10 mm	TS3S5010S		
		11.5 mm	TS3S5011S		
		13 mm	TS3S5013S		
Straumann BLX (K173961, K181703, K191256)	3.5	8	061.3308	Regular Base (RB)	 TorcFit connection
		10	061.3310		
		12	061.3312		
		14	061.3314		
		16	061.3316		
		18	061.3318		
	3.75	6	061.4306		
		8	061.4308		
		10	061.4310		
		12	061.4312		
		14	061.4314		
		16	061.4316		
		18	061.4318		
	4.0	6	061.5306		
		8	061.5308		
		10	061.5310		
		12	061.5312		
		14	061.5314		
		16	061.5316		
		18	061.5318		
	4.5	6	061.6306		
		8	061.6308		
		10	061.6310		
		12	061.6312		
		14	061.6314		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		16	061.6316		
		18	061.6318		
	5.0	6	061.7306	Wide Base (WB)	
		8	061.7308		
		10	061.7310		
		12	061.7312		
		14	061.7314		
		16	061.7316		
		18	061.7318		
	5.5	6	061.8306		
		8	061.8308		
		10	061.8310		
		12	061.8312		
	6.5	6	061.9306		
		8	061.9308		
		10	061.9310		
		12	061.9312		
Straumann Bone Level Implants SC (K162890)	2.9	10	021.0010	Small Crossfit (SC)	 Internal Cross Fit®
		12	021.0112		
		14	021.0114		
Straumann Bone Level Implants NC, RC (K140878)	3.3	8	021.3508	Narrow Crossfit (NC)	
		10	021.3510		
		12	021.3512		
		14	021.3514		
		16	021.3516		
		18	021.3518		
	4.1	8	021.5508	Regular Crossfit (RC)	
		10	021.5510		
		12	021.5512		
		14	021.5514		
		16	021.5516		
		18	021.5518		
	4.8	8	021.7508		
		10	021.7510		
		12	021.7512		
		14	021.7514		

Implant System	Implant Body Diameter (mm)	Implant Length (mm)	Model No.	Implant Platform Diameter (mm)	Type of Implant-Abutment Connection
		16	021.7516		
		18	021.7518		
Zimmer 3.1mmD Dental Implant System (K142082)	3.1	8mm	CM318	2.9	 Internal Hex
		10mm	CM3110		
		11.5mm	CM3111		
		13mm	CM3113		
		16mm	CM3116		
Screw Vent® and Tapered Screw Vent® (K013227)	3.7	8mm	TSVTB8	3.5	
		10mm	TSVTB10		
		11.5mm	TSVTB11		
		13mm	TSVTB13		
		16mm	TSVTB16		
	4.1	8mm	TSVT4B8	3.5	
		10mm	TSVT4B10		
		11.5mm	TSVT4B11		
		13mm	TSVT4B13		
		16mm	TSVT4B16		
	4.7	8mm	TSVTWB8	4.5	
		10mm	TSVTWB10		
		11.5mm	TSVTWB11		
		13mm	TSVTWB13		
		16mm	TSVTWB16		
	6.0	8mm	TSVT6B8	5.7	
		10mm	TSVT6B10		
		11.5mm	TSVT6B11		
		13mm	TSVT6B13		
		16mm	TSVT6B16		

Summary of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows at the end of this section.

AOT & T-L Abutment

1) AOT Abutment

	Subject Device	Predicate Devices
Part Name	**AOT Abutment**	**Multi-unit Straight Abutment**
Design		
Applicant	TruAbutment Inc.	TruAbutment Korea Co., Ltd.
Trade Name	AOT & T-L Abutment	URIS OMNI Narrow System & Prosthetic
510(K) No.	-	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)
Indication For Use/ Intended Use	AOT & T-L Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit restorations. It is compatible with the following systems: • Astra OsseoSpeed EV(K130999) 3.0 • Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm • Dentium Company Limited Implantium (K041368): 3.6, 4.0, 4.5, 5.0 (Regular) • Implant Direct Legacy2(K192221) 3.0 • Megagen AnyRidge Internal Implant	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.

	System (K140091) 3.5, 4.0, 4.4, 4.9, 5.4 (3.1) • Neodent Implant System - GM Helix (K163194, Kl80536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0) • Nobel Active 3.0 (K102436) 3.0 • Nobel Active Internal Connection Implant (K071370) NP RP 3.5, 4.3, 5.0 • Nobelactive Wide Platform (Wp) (K133731) WP 5.0 • TS Fixture System (K121995) 3.5 (3.75) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1) mm (Mini, Regular) • Straumann BLX Implant (Kl73961, Kl81703, K191256) 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB) • Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (Kl62890) 2.9 (SC) • Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC) • Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9) • Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.1(3.5), 4.7(4.5), 6.0(5.7)	
Diameters	4.8mm	5.0mm
Lengths	G/H :1.0/2.0/3.0mm	G/H :1.0/2.0/3.0/4.0/5.0/6.0mm
Surface Treatment	None	None
Sterile	Non-sterile	Non-sterile
SE	The subject device (AOT & T-L Abutment) is substantially equivalent to the predicate device (URIS OMNI Narrow System & Prosthetic, K200817). 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 subject device and the primary predicate device are related to the compatible OEM implant lines and the implant platform diameter. The diameter of the primary predicate device is Ø5.0mm, while the subject device is Ø 4.8mm. The cuff height of the primary predicate device is 1.0mm~ 6.0mm, while the subject device can be designed from 1.0mm up to 3.0mm.	

2) T-L Abutment

	Subject Device	Predicate Devices
Part Name	**T-L Abutment**	**T LOC Straight Abutment**
Design		
Applicant	TruAbutment Inc.	TruAbutment Korea Co., Ltd.
Trade Name	AOT & T-L Abutment	URIS OMNI Narrow System & Prosthetic
510(K) No.	-	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)
Indication For Use/ Intended Use	AOT & T-L Abutment is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of multiple-unit restorations. It is compatible with the following systems: • Astra OsseoSpeed EV(K130999) 3.0 • Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm • Dentium Company Limited Implantium (K041368): 3.6, 4.0, 4.5, 5.0 (Regular) • Implant Direct Legacy2(K192221) 3.0 • Megagen AnyRidge Internal Implant System (K140091) 3.5, 4.0, 4.4, 4.9, 5.4 (3.1) • Neodent Implant System - GM Helix (K163194, Kl80536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0) • Nobel Active 3.0 (K102436) 3.0 • Nobel Active Internal Connection	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.

	Subject Device	Predicate Devices
Part Name	**T-L Abutment**	**T LOC Straight Abutment**
	Implant (K071370) NP RP 3.5, 4.3, 5.0 • Nobelactive Wide Platform (Wp) (K133731) WP 5.0 • TS Fixture System (K121995) 3.5 (3.75) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1) mm (Mini, Regular) • Straumann BLX Implant (Kl73961, Kl81703, K191256) 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB, WB) • Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (Kl62890) 2.9 (SC) • Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC) • Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9) • Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.1(3.5), 4.7(4.5), 6.0(5.7)	
Diameters	3.89mm	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 (AOT & T-L Abutment) is substantially equivalent to the predicate device (URIS OMNI Narrow System & Prosthetic, 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. The minor differences between the subject device and the primary predicate device are related to the compatible OEM implant lines and the implant platform diameter. The diameter of the primary predicate device is Ø3.8mm, while the subject device is Ø 3.89mm.	

3) AOT Component

	Subject Device	Predicate Devices
Part Name	**AOT Temporary**	**Multi-unit Temporary Cylinder**
Design		
Applicant	TruAbutment Inc.	TruAbutment Korea Co., Ltd
Trade Name	AOT & T-L Abutment	URIS OMNI Narrow System & Prosthetic
510(K) No.	-	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)
Indication For Use/ Intended Use	AOT Temporary 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.	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.
Diameters	4.8mm	5.0mm
Lengths	12mm	12mm
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 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	Predicate Devices
Part Name	**AOT Base**	**Multi-unit Base**
Design		
Applicant	TruAbutment Inc.	TruAbutment Korea Co., Ltd
Trade Name	AOT & T-L Abutment	URIS OMNI Narrow System & Prosthetic
510(K) No.	-	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)
Indication For Use/ Intended Use	AOT 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.	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.
Diameters	5.3mm	5.0mm
Lengths	4.35/7.35mm	4.35/7.35mm
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 characteristic, and are made of similar materials. The subject device and predicate devices have similar physical dimensions, including diameter. The diameters of the subject device are slightly different from the predicate devices. However, this dimensional difference doesn’t affect substantial equivalence.	

	Subject Device	Predicate Device
Part Name	**AOT Base Screw/AOT Plus Screw /Multi Unit Direct Screw**	**Multi-unit Cylinder Screw**
Design		
Applicant	TruAbutment Inc.	TruAbutment Korea Co., Ltd
Trade Name	AOT & T-L Abutment	URIS OMNI Narrow System & Prosthetic
510(K) No.	-	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)
Indication 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	2.2mm / 2.25mm	1.6mm
Lengths	3.6mm / 4.4mm	3.3mm
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 characteristic, 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 3.6mm , 4.4mm.	

Substantial Equivalence Discussion

The subject device (AOT & T-L Abutment) is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. The provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device.

The Indications for Use Statement (IFUS) for the subject device (AOT & T-L Abutment) is substantially equivalent in intended use to the primary predicate device (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.

Slight differences in the language of the subject device (AOT & T-L Abutment) and primary predicate (K200817) Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. The minor differences between the subject device (AOT & T-L Abutment) and the primary predicate device (K200817) are related to the compatible OEM implant lines and the implant platform diameter.

The subject devices (AOT & T-L Abutment) are to be sterilized by the end-user, the same as primary predicate devices (K200817). Sterilization validation for the subject devices (AOT & T-L Abutment) was performed according to ISO 17665-1 and ISO 17665-2. This sterilization validation method is the same as the primary predicate devices (K200817).

Mechanical performance testing was performed according to ISO 14801. For compatible OEM implant line, worst-case constructs were subjected to static compression and compression fatigue testing. The fatigue limit data for all other implant lines demonstrated the construct strengths to be substantially equivalent to the predicate device..

Non-clinical Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Test according to ISO 14801:2016

Below tests were performed for predicate device (K152559, K200817) and leveraged for the subject device:

- End User Steam Sterilization Test according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010.
- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Non-clinical test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device. The results of the above tests have met the criteria of the standard, and demonstrated the substantial equivalence with the predicate device.

Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible OEM implant body, OEM abutment, and OEM fixation screw. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate devices.

Comparative fatigue testing of the subject and predicate devices was conducted in accordance with ISO 14801 and FDA Guidance "Class II Special Controls Guidance Document: Rootform Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems.

Conclusion

The AOT & T-L Abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, AOT & T-L Abutment and its predicate are substantially equivalent.