September 13, 2024

DenQ
Taehoon Lee
Representative
302, PNU Hyowon Industry-Academic Cooperation Hall, 2,
Busandaehak-ro, Geumjeong-gu
Busan, 46241
REPUBLIC OF KOREA

Re: K240977
Trade/Device Name: DenQ Sub SLA Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 14, 2024
Received: August 14, 2024

Dear Taehoon Lee:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240977

Device Name

DenQ Sub SLA Implant System

Indications for Use *(Describe)*

The DenQ Sub SLA 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 terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary

Submitter

DENQ
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Device Information

Trade Name: DenQ Sub SLA Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 09/13/2024

Predicate Device(s)

Primary Predicate Device

- K222707-IH Implant System, Sewon Medix Inc.

Reference Devices

- K121995-TS Fixture System, OSSTEM Implant Co., Ltd.
- K213576-Tatum Surgical Dental Implant System, Suncoast Dental, Inc. dba Tatum Surgical
- K230108-Straumann® BLC and TLC Implants, Straumann USA, LLC
- K153521-IH Implant System, Sewon medix Inc.

Description

The DenQ Sub SLA Implant System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. This implant system has internal hex connection, tapered with straight body and bone level that are similar to other commercial available products based on the intended use, technology used, the material composition employed and performance characteristics. This DenQ Sub SLA fixture of implant system is supplied sterile.

The DenQ Sub SLA Implant System diameter and lengths are below:

- The DenQ Sub SLA Fixtures

Internal Hex-connected, Bone level fixture, Tapered and Tapered-Straight body
Implant Fixture Dimension:

Product name	Division	Platform Diameters (Fixture Diameter)	Body Diameters	Lengths
Fixture I	Regular	Ø3.75, Ø3.77	-	7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15 mm
		Ø4.25	-	
		Ø4.6, Ø4.63, Ø4.65	-	
		Ø5.05, Ø5.08. Ø5.1	-	
	Wide	Ø5.95	-	
		Ø6.8	-	
Fixture II	Regular	Ø4.21	Ø4.0	7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14 mm
		Ø4.67	Ø4.5	
		Ø5.14	Ø5.0	
	Wide	Ø6.2	Ø5.0	
		Ø6.8	Ø5.8	
Fixture III	Regular	Ø4.25	-	7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14 mm
		Ø4.6, Ø4.63, Ø4.65	-	
		Ø5.05, Ø5.08. Ø5.1	-	
	Wide	Ø5.95	-	
		Ø6.8	-	

The fixture is made of Pure Titanium Grade 4. The surface is treated by Sand –blasting (Large grit) and acid etching method (SLA). This system only contains the implant bodies with cover screw and are provided as a set-packing.

The DenQ Sub Abutments are device made of cp titanium grade 4 and titanium alloy intended for use as a Prosthetic restoration. It consists of Abutments(Healing, Solid, Cement, Angled, Temporary, Multi-unit Straight, Multi-unit Angled, Multi-unit Healing Cap, Multi-unit Ti Cylinder, Multi-unit Temporary Cylinder and FreeMilling). The TiN coating is applied to some abutment, which are solid Abutment, Cement Abutment and Angled Abutment. They have various diameter, height(Length), gingiva height, post height and angled. The Healing Abutment has various diameter 4, 4.5, 5.0, 5.5, 6.0, 6.5 and 7.0, Lengths 8.4, 9.4, 10.4, 11.4 and 12.4mm. The Solid Abutment packaging is only abutment that has various diameters 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 and 7.0, gingiva height 0.5, 1, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 and 5mm, post height 4, 5.5 and 7mm. The Cement Abutment has various diameters 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 and 7.0, gingiva height 0.5, 1, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 and 5mm, post height 4, 5.5 and 7mm. The Angled Abutment has post angled 15°, 17°, 20° and 25°. Its packaging is Abutment with Abutment screw and it has hex and non-hex type. The angle abutment has diameter 4.0, 4.5, 5.0, 5.5 and 6.0mm, gingiva height 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 and 5.0mm, post height 8mm. It has hex and non-hex, hex type of a and b that a type is same path for post height with hex's edge and b type is same path for hex's plat with post height. Its packaging is abutment with abutment screw as a set packaging. The temporary abutment has diameter 4.0, 4.5, 5.0, 5.5 and 6.0mm, gingiva height 0.5, 1.0, 1.5, 2.0, 2.5 and 3.0mm, height 12.6, 13.1, 13.6, 14.1, 14.6, 15.1 and 12.85, 13.35, 13.85, 14.35, 14.85 and 15.35. Its packaging unit is abutment with abutment screw as a set. The multi-unit Abutment consist straight and angled type and straight type has diameter 4.8, 5.0 and 5.5mm, gingiva height 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 and 5.0mm, the hex of abutment 2.0mm, hex height 2.2mm. And angled type has diameter 4.71, 4.92, 5.04, 5.4 and

5.5mm, angle 15°, 17°, 20° and 30°, gingiva height 1.0, 2.0, 2.5, 3.0, 3.5, 4.0 and 4.5. Its packaging unit is abutment with abutment screw as a set. It has hex and non-hex. The multi-unit healing cap has various diameter 4.5, 4.8, 5.0 and 5.5mm, height 4.8 and 5.0mm. The multi-unit Ti cylinder has diameter 4.5, 4.8, 5.0 and 5.5mm, post height 4.1, 5.6 and 7.1mm. Its packaging unit is Ti cylinder with cylinder screw as a set. The multi-unit temporary cylinder has various diameter 4.5, 4.8, 5.0 and 5.5mm, length 12mm. Its packaging unit is temporary abutment with cylinder as a set. The FreeMilling abutment has various diameter 4.5, 5.0, 5.5 and 6.0mm, gingiva height 1, 2, 3, 4 and 5mm, length 15.5 and 15.75mm. It has hex and non-hex and packaging unit is abutment with abutment screw. It is used by hand milling. Its packaging unit is abutment with abutment screw as a set.
Healing Abutment, Temporary Abutment, Multi-unit Abutment and Temporary Abutment are uncoating applied. All Abutment is supplied non-sterilized and should be sterilized before use as given conditions of manufacturer.

Indication for Use

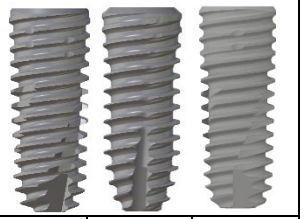
The DenQ Sub SLA Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

Predicate Device and reference devices & Comparison of Fixture

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

- K222707, IH Implant System by Sewon Medix Inc. – Primary predicate device
- K121995, TS Fixture System by Osstem Implant Co., Ltd. – Reference device
- K213576, Tatum Surgical Dental Implant System by Suncoast Dental, Inc. dba Tatum Surgical. – Reference device
- K230108, Straumann® BLC and TLC Implants by Straumann USA, LLC – Reference device

Division	**Subject Device**	**Primary Predicate device**	**Reference device**		
Trade Name	DenQ Sub SLA Implant System	IH Implant System	TS Fixture System	Tatum Surgical Dental Implant System	Straumann® BLC and TLC Implants
510(k) Number	**K240977**	**K222707**	**K121995**	**K213576**	**K230108**
Manufacturer	DenQ Co., Ltd.	Sewon Medix Inc.	Osstem Implant Co., Ltd.	Suncoast Dental, Inc. dba Tatum Surgical	Straumann USA, LLC
Reason for primary and Reference device	N/A	Major technological characteristics	Implant body shape, wide diameter(Ø6.2, 6.8) and length(7~12.5mm)	Implant wide diameter(Ø6.0, 7.0) and length(13~15mm)	Basic surface treatment, implant body diameter and length
Indication for use	The DenQ Sub SLA Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including;	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit	The TS Fixture System is indicated for use in partially or full edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained,	The Tatum Surgical Integrity Tapered, "T" and "S" Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw to provide support for	Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for

	cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.	restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	screw retained, or overdenture restorations; and final or temporary abutment support for fixed bridgework, It is intended for delayed loading.	removable or fixed prosthesis to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.
Material	CP Titanium Gr.4 (ASTM F67-13)	CP Titanium Gr.4 (ASTM F67-13)	CP Titanium Gr.4 (ASTM F67-13)	Ti 6Al 4V (ASTM F136-13)	Titanium-13 Zirconium alloy (Roxolid®)
Design (Fixture Type)	 I II III				
Fixture Diameter	Fixture I Reg.: Ø3.75, Ø3.77, Ø4.25, Ø4.6, Ø4.63,	Mini: Ø3.7 Reg.: Ø3.8, Ø4.2, Ø4.5, Ø5.0, Ø5.95	TSII SA Fixture Ø3.5, Ø4.2, Ø4.4, Ø4.9 TSIII SA Fixture	Ø3.7, 4.0, Ø4.5, Ø5.0, Ø6.0, Ø7.0, Ø8.0	Ø3.3, Ø3.75, Ø4.5, Ø5.5, Ø6.5

	Ø4.65, Ø5.05, Ø5.08, Ø5.1 Wide: Ø5.95, Ø 6.8 Fixture II Reg.: Ø4.21, Ø4.67, Ø5.14 Wide: Ø6.2, Ø6.8 Fixture III Reg.: Ø4.25, Ø4.6, Ø4.63, Ø4.65, Ø5.05, Ø5.08, Ø5.1 Wide: Ø5.95, Ø 6.8		Ø3.75, Ø3.77, Ø4.2, Ø4.25, Ø4.6, Ø4.63, Ø4.65, Ø5.05, Ø5.08, Ø5.1 TSIII SA Ultra-Wide Fixture Ø5.92, Ø5.95, Ø6, Ø6.8		
Fixture Length	Fixture I 7~15mm Fixture II, III 7~14 mm	7.0, 8.5, 10, 11.5, 13, 15 mm	TS Fixture 7~15 mm TS III SA Ultra-Wide Fixture 7~12.5 mm	9, 11, 14, 17, 20 mm (no 20 mm length for Ø7 and 8 mm)	BLC: Ø3.3: 8~18mm Ø3.75 and Ø4.5: 6~18mm Ø5.5: 6~16mm Ø6.5: 6~14mm TLC: Ø3.3, Ø3.75 and Ø4.5 of BLC are same Ø5.5: 6~12mm Ø6.5: 6~10mm
Structure	- Internal Hex-connected -Bone level - Tapered & straight body shape - Cutting edge with self-tapping - 0.8mm thread pitch	- Internal Hex-connected -Bone level - Tapered body shape - Cutting edge with self-tapping - 0.8mm thread pitch	- Internal Hex-connected -Bone level - Tapered body shape and straight body shape - 4 sided cutting edge with self-tapping	- Tissue or Bone Level - Threaded - Tapered body - Root-form implant	Apically tapered Bone Level implant

Connection type	Internal hex connection	Internal hex connection	Internal hex connection	Internal Pentagon connection	TorcFit(with conical fitting)
Surgery type	One or two stage	One or two stage	One or two stage	One or two stage	One or two stage
Surface Treatment	SLA	SLA	SA(SLA)	Aluminum oxide blasted and passivated	Hydrophilic SLActive® and SLA®
Gamma Sterilized	Yes	Yes	Yes	Yes	Yes
Product Code	DZE, NHA	DZE, NHA	DZE	DZE, NHA	DZE
Shelf Life	5 years	5 years	8 years	5 years	5 years
S.E	The Indication for use of DenQ Sub SLA Implant System is similar to the primary predicate device as K222707. Also, the indication for use of reference devices K121995, K213576 and K230108 are the similar to the Subject device. The DenQ Sub SLA Implant System has taper body of fixture I, III and taper-straight-taper body shape of fixture II. The DenQ Sub SLA Implant System has the similar raw material, surface treatment, surgical type, sterilization method, shelf-life, connection structure, implant basic components and product code as primary predicate device K222707. The difference between the Subject device and primary predicate device are their similar implant body shape, implant diameter, and length. The implant shape and configuration were similar to the primary predicate device and reference device, with bone level, tapered and straight body, cutting edge, and self-tapping structures. The Subject device has tapered body and tapered-straight-tapered body shapes, but the primary device K222707 has only tapered body shape. However, the reference device K121995 has an implant body shape with tapered and straight body shapes, and the body shape of subject device and reference device K121995 are very similar. The implant diameter of subject device ranges from Ø3.75 to Ø6.8(Ø3.88, Ø3.9 of Fixture II and Ø3.77 of Fixture III are not available), and these diameters have a similar range to the diameter of primary predicate device. However, implant diameters of Ø6.2 and Ø6.8 are not included in the primary predicate device. The implant diameters Ø6.2 and Ø6.8 are similar to the reference device K122995 wide implant Ø6.0 and Ø6.2 of implant diameter of subject device, and the subject device Ø6.8 diameter is similar to Ø6.8 diameter of reference device K122995. The implant length of the Subject device is 7~15mm, and the implant length of the primary predicate device is 7~15mm, but Ø5.95 is 7~13mm and there is no 15mm. The implant lengths of Subject device Ø6.2 and Ø6.8x7~15mm are similar to Ø5.92, Ø5.95, Ø6.8x7~12.5mm in reference device K121995. The implant				

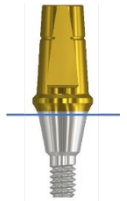
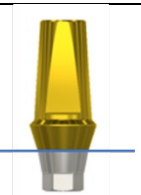
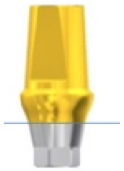
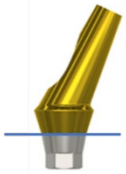
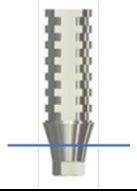
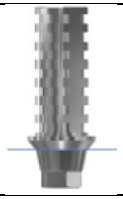
	lengths of Subject device Ø5.95x15mm, Ø6.2 and Ø6.8x13~15mm are similar to the Ø6.0, Ø7.0x11~17mm of the reference device K213576. The subject device consists of an implant body with a diameter of 3.7 to 6.8, and the K230108 consists of an implant body with a diameter of 3.3 to 6.5, which constitute implant body diameters similar to those of the subject device and K230108. The Subject device has sand blasting and acid etching surface it is similar primary device K222707 and the basic surface treatment method is the similar as the reference device K230108.

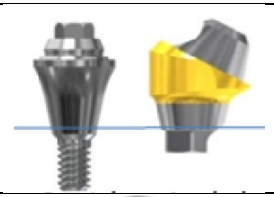
Reference Devices & Comparison of Abutment

The subject device is substantially equivalent to the following reference device:

- K153521, IH Implant System by Sewon Medix Inc. – Reference device

Division	Subject Device	Reference Device
Trade Name	**DenQ Sub SLA Implant System**	**IH Prosthetic System**
510(k) Number	**K240977**	**K153521**
Manufacturer	DenQ Co., Ltd.	Sewon Medix Inc.
Indication for use	The DenQ Sub SLA 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 terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.
Material	Ti 6Al 4V ELI (ASTM F136-13) Healing, Solid, Cement, Multi-unit CP Titanium Gr4 (ASTM F67-13) Angled, Temporary, FreeMilling	Ti 6Al 4V ELI (ASTM F136) Healing, Solid, Cement, Multi-unit CP Titanium Gr4 (ASTM F67-13) Angled, Temporary, FreeMilling

Design (Abutment)	Healing		
	Solid		
	Cement		
	Angled		
	Temporary		

	Multi-unit (St. & Angled)		
	FreeMilling		
Description		This product is a bone level dental implant Abutment(Endosseous Dental Abutment). It is a dental implant to support and maintain dentures by implanting a fixture into jawbones and prosthetic restoration in case of partial or total loss of natural teeth. This product is excellent biocompatibility, it is aesthetically treated by mechanical and physical coating treatment on titanium alloy. This dental implant superstructure can use cement-fixed and screw fixed prostheses. It is mechanically connected to the bone level dental implant fixture.	Healing Abutment is used to make a soft tissue shape before setting up prosthetics and removing cover screw after osteointegration. Angled Abutment is an abutment which has certain angle to easy for adjustment of installation angle of prosthesis. Temporary Abutment is used temporary until final prosthesis is made to maintain esthetic appreciation and chew ability. Multi-Unit Abutment is used for screw retained multiple case. Solid, Cement and FreeMilling Abutment to fabricate a prosthesis of internal single & bridge cement retained type.
Dimension	**Healing**	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0 G/H Length: - Post length: -	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5 G/H Length: - Post length: -
	Solid	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0 G/H: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm P/L: 4, 5.5, 7mm	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0 G/H: 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm P/L: 4, 5.5, 7mm

	Cement	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0 G/H: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm P/L: 4, 5.5, 7mm	Dia.: Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5 G/H: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm P/L: 4, 5.5, 7mm
	Angled	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0 G/H: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm P/L: 8mm Angle: 15°, 17°, 20°, 25°	Dia.: Ø4.5, Ø5.0, Ø5.5, Ø6.0 G/H: 2.0, 3.0, 4.0mm P/L: 7.5, 8mm Angle: 15°, 25°
	Temporary	Dia.: Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0 G/H: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0mm P/L: -	Dia.: Ø4.0, Ø4.5 G/H: 1.0, 3.0mm P/L: -
	Multi-unit (St.)	Dia.: Ø4.8, Ø5.0, Ø5.5 G/H: 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm P/L: 2.2mm	Dia.: Ø4.8 G/H: 1.5, 2.5, 3.5, 4.5mm P/L: 2.2mm
	Multi-unit (Angled)	Dia.: Ø4.71, Ø4.92, Ø5.04, Ø5.4, Ø5.5 G/H: 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5mm P/L: - Angled: 15°, 17°, 20°, 25°, 30°	Dia.: Ø4.7, Ø5.13 G/H: 2.5, 3.5, 4.5mm P/L: - Angled: 17°, 30° -
	FreeMilling	Dia.: Ø4.5, Ø5.0, Ø5.5, Ø6.0 G/L: 1.0, 2.0, 3.0, 4.0, 5.0mm H: 8, 9, 10, 11, 12mm	Dia.: Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5 G/H: 1.0, 2.0, 3.0mm P/L: 10, 11, 12mm
Structure		Internal Hex	Internal Hex
Connection type		Screw & Internal Hex-Connected	Screw & Internal Hex-Connected
Surface		Machined or TiN	Machined or TiN
Sterilization		Non-Sterile	Non-Sterile

Product Code	NHA	NHA	
Technological Characteristics	The DenQ Sub Abutment is similar indication for use, Materials, Structure, Connection type, Surface, Sterilization, and product code as the reference device(K153521). But dimension is included reference device(K153521). And the design(shape) and description are similar with reference device(K153521). But it is different characteristics for each abutment as blow;		
	1. Shape(TiN coating applied)		
	-	DenQ Sub Abutment	Reference device
	Multi-unit(Angled)	Non-applied	Partial applied
	2. Dimension(Diameter)		
	-	DenQ Sub Abutment	Reference device
	Healing	Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0	Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5
	Cement	Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0	Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5
	Temporary	Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0	Ø4.0, Ø4.5
	Multi-unit Straight	Ø4.8, Ø5.0, Ø5.5	Ø4.8
	Multi-unit Angled	Ø4.71, Ø4.92, Ø5.04, Ø5.4, Ø5.5	Ø4.7, Ø5.13
	FreeMilling	Ø4.5, Ø5.0, Ø5.5, Ø6.0	Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5
	3. Dimension(G/H Length)		
	-	DenQ Sub Abutment	Reference device
	Multi-unit Straight	0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0mm	1.5, 2.5, 3.5, 4.5mm
	Multi-unit Angled	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5mm	2.5, 3.5, 4.5mm
	Temporary	0.5, 1.0, 1.5, 2.0, 2.5, 3.0mm	1.0, 3.0mm
	4. Dimension(Post Length)		
	-	DenQ Sub Abutment	Reference device
	Angle	8mm	7.5, 8mm

	Temporary	8, 9, 10, 11, 12mm	10, 11, 12mm
	5. Dimension(Angle)		
	-	DenQ Sub Abutment	Reference device
	Angled	15°, 17°, 20°, 25°	15°, 25°
	Multi-unit(Angled)	15°, 17°, 20°, 25°, 30°	17°, 30°

Substantial Equivalence Discussion

The DenQ Sub SLA Fixture has similar indication for use, material, surface treatment, surgery type, sterilization method, connection type, shelf life, product code and similar design, structure, diameter and length and technological characteristic as the primary predicate device(K222707). The wide implant diameter and length of subject device differ from the primary predicate device. The reference device K122995 and K213576 support substantial equivalence of subject device's wide implant diameters and lengths. The basic surface treatment of reference device K230108 supports substantial equivalence to subject device's surface treatment.
The DenQ Sub Abutment is similar indication for use, materials, structure, connection type, surface, sterilization, and product code as the device but, the technological characteristic is difference that is coating area and dimensions between subject device and reference device and the angle is included in the range of the abutment of the reference device. The coating area, dimension, and angle of abutment of reference device K153521 support substantial equivalence of coating area, dimension, and angle of abutment of subject device.

The DenQ Sub SLA System has been subjected to performance and product validations prior to release. Testing including biocompatibility has been performed to ensure the devices comply with the applicable International and US regulations.
The differences between the subject device and reference devices are detailed shape and detailed dimension of diameter, length, angle, gingiva height, post height and coating area.

Summary of non-clinical test data

The following tests, verification and validations were performed in accordance with ISO standard, FDA recognized standards and US regulations.

- Gamma Sterilization Validation test according to ISO 11137-1, -2
- Shelf-life Validation test according to ISO 11607-1, ISO 11607-2, ASTM F1980-16, ASTM F1140-13, ASTM F1929-15, ASTM F2096-11 and ASTM F88/F88M-15

- BET Validation test according to USP <85><161>
- User Sterilization Validation test according to ISO 17665-1, -2
- Biocompatibility test according to ISO 10993-1 and ISO 14971
- Fatigue test according to ISO 14801
- Shear testing was performed per ASTM F1044
- Tension testing was performed per ASTM F1147
- Abrasion characteristics was determined by a scratch test drawn across the coated surface under an increasing load (either stepwise or continuous) until at some load (termed as critical load) a well-defined failure event occurs. Information clearly indicating the test protocol, selection of the load range used for the scratch test, type of indenter used to perform the scratch on the surface, depth of the scratch with respect to the applied load, failure event selection criteria, and high magnification images clearly demonstrating the coating detachment was provided.
- Surface analysis according to the FDA guidance document including SEM/EDS analysis.

The fatigue test for DenQ Sub straight type Abutment and DenQ Sub SLA Fixture and DenQ Sub Angled Abutment and DenQ Sub SLA Fixture were 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-Implant-Dynamic loading test for endosseous dental implant. This was tested based on the worst-case scenario, results were compliant and similar to previously cleared primary predicate devices. Those tests have been performed to evaluate the substantial equivalence in the surface characteristics compared to the primary predicate device. The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the primary predicate device. The results of the non-clinical testing demonstrate that the subject device is substantially equivalent to the primary predicate device.

MR Environment: MR Conditional

Non-clinical worst-case MRI review was performed to evaluate the metallic DenQ Sub SLA Implant System devices in the MRI environment using scientific rationale and published literature (i.e., 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, no.2 (March/April 2021): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws)

and material compositions. The 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."

Summary of clinical testing

No clinical testing was performed for this submission.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification DenQ concludes that the *DenQ Sub SLA Implant System* is substantially equivalent to the primary predicate devices as described herein.