TECHWIN Co., Ltd.
℅ Kyung-Hwan Kim
Representative Consultant
SMB Korea
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Seoul, 07071
REPUBLIC OF KOREA

August 20, 2024

Re: K231932
Trade/Device Name: TDS (TECHWIN DENTAL SYSTEM)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 16, 2024
Received: July 23, 2024

Dear Kyung-Hwan 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231932

Device Name
TDS (TECHWIN DENTAL SYSTEM)

Indications for Use *(Describe)*
The TDS (TECHWIN DENTAL SYSTEM) are prefabricated prosthetic components for direct connection to endosseous dental implants and are intended to be used as an aid in prosthetic rehabilitation. It is intended for use in edentulous and partially edentulous patients with established bone and completed growth period to support single unit prosthetic restorations in the mandible or maxilla. It is intended for one-stage and two-stage surgical procedures. This system is intended for delayed loading.

The TDS (TECHWIN DENTAL SYSTEM) is compatible with the following devices:

No.	Subject Device	Implantable Diameters (mm)	Compatible Implants (510k No.)/Manufacture	Type of Implant Abutment Connection/	Implant Platform Type	Implant Platform Platform Diameters(mm)	Implant Body Diameter (mm)
1.	Dual Abutment	Ø4.0, 4.6	Chaorum Implant System (K160536)/ MEDIMECCA CO., LTD.	Hex or non-hex/ 2.1 Hex	Narrow (mini)	Ø3.25, 3.89	Ø3.0, 3.5
		Ø4.5, 4.6, 5.0, 5.5, 6.0, 6.5, 7.0		Hex or non-hex/ 2.5 Hex	Wide (Regular)	Ø3.89, 4.28, 4.78, 5.28, 6.28	Ø3.9, 4.0, 4.4, 4.5, 4.9, 5.5, 5.9
2.	Healing Abutment	Ø4.3, 4.8		Hex or non-hex/ 2.1 Hex	Narrow (mini)	Ø3.25, 3.89	Ø3.0, 3.5
		Ø4.0, 4.3, 4.5, 4.6, 4.8, 5.3, 5.5, 5.6, 6.3. 6.5, 7.3, 7.5, 8.3, 8.5		Hex or non-hex/ 2.5 Hex	Wide (Regular)	Ø3.89, 4.28, 4.78, 5.28, 6.28	Ø3.9, 4.0, 4.4, 4.5, 4.9, 5.5, 5.9
3.	Abutment Screw	Ø2.22		-	Narrow (mini)	-	-
		Ø2.1, 2.3, 2.32, 2.5		-	Wide (Regular)	-	-

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
For
TDS (TECHWIN DENTAL SYSTEM)

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

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II. SUBMISSION CORRESPONDENT

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Email: info@smbkorea.com

III. DATE PREPARED

August 19, 2024

IV. DEVICE

Trade or Proprietary Name:	TDS (TECHWIN DENTAL SYSTEM)
Common or Usual Name:	Endosseous Dental Implant Abutment
Classification Name:	Abutment, Implant, Dental, Endosseous (872.3630)
Regulatory Class:	II
Product Code:	NHA
Classification Panel:	Dental

V. PREDICATE DEVICE

Primary Predicate Device:
K160536, Chaorum Implant System / Medimecca Co., Ltd.

VI. DEVICE DESCRIPTION

The TDS (TECHWIN DENTAL SYSTEM), made of Ti-6A1-4V ELI alloy (ASTM F136), is intended for use in conjunction with the appliance in partially or fully edentulous mandibles and maxillae to support single-unit loading (i.e., crown). It consists of the Dual Abutment and Healing Abutment. The surface of the abutments is uncoated or partially or half coated with TiN using AIP (Arc Ion Plating). The implant-to-abutment interface remains uncoated. All abutments are supplied non-sterile and must be autoclaved by the end-user.

The TDS (TECHWIN DENTAL SYSTEM) is compatible with the following devices:

No.	510k No.	Trade Name	Platform Type	Platform Diameters (mm)	Manufacture
1.	K160536	Chaorum Implant System	Narrow	Ø3.25~3.89	MEDIMECCA CO., LTD.
			Regular	Ø3.89~6.28	

The abutment's dimension range is as follows:

Abutment	Diameter (ø)	Post Height (mm)	Total Length (mm)	Cuff Height (mm)	Angulation (°)	Surface
Dual Abutment	4.0, 4.5, 4.6, 5.0, 5.5, 6.0, 6.5, 7.0	4.0, 5.5, 7.0	7.5, 8.5, 9.0, 9.1, 9.2, 9.5, 9.7, 10.0, 10.1, 10.5, 10.6, 10.7, 10.85, 11.0, 11.1, 11.2, 11.5, 11.6, 11.7, 11.85, 12.0, 12.1, 12.2, 12.5, 12.6, 12.7, 12.85, 13.0, 13.1, 13.2, 13.5, 13.6, 13.7, 13.85, 14.0, 14.2, 14.5, 14.6, 14,85, 15.2	1.0, 1.3, 1.8, 2.3, 2.8, 3.3, 3.8, 4.3, 4.8, 5.3	-	TiN coating
Healing Abutment	4.0, 4.3, 4.5, 4.6, 4.8, 5.3, 5.5, 5.6, 6.3, 6.5, 7.3, 7.5, 8.3, 8.5	2.0, 3.0, 3.5, 4.0, 5.0, 5.5, 7.0	7.5, 8.5, 8.7, 9.5, 10.5, 11.0, 11.5, 12.0, 12.5, 14.0, 14.5	1.0, 2.0, 3.0, 4.0, 5.0	-	Non/TiN coating
Abutment Screw	2.1, 2.22, 2.3, 2.32, 2.5	-	8, 8.35, 8.5, 8.8, 9.8, 10.1, 10.2	-	-	Machined

VII. INDICATION FOR USE

The TDS (TECHWIN DENTAL SYSTEM) are prefabricated prosthetic components for direct connection to endosseous dental implants and are intended to be used as an aid in prosthetic rehabilitation. It is intended for use in edentulous and partially edentulous patients with established bone and completed growth period to support single unit prosthetic restorations in the mandible or maxilla. It is intended for one-stage and two-stage surgical procedures. This system is intended for delayed loading.

The TDS (TECHWIN DENTAL SYSTEM) is compatible with the following devices:

No.	Subject Device	Implantable Diameters (mm)	Compatible Implants (510k No.)/ Manufacture	Type of Implant – Abutment Connection/ Diameter (mm)	Implant Platform Type	Implant Platform Diameters (mm)	Implant Body Diameters (mm)
1.	Dual Abutment	Ø4.0, 4.6	Chaorum Implant System (K160536)/ MEDIMECCA CO., LTD.	Hex or non-hex/ 2.1 Hex	Narrow (mini)	Ø3.25, 3.89	Ø3.0, 3.5
		Ø4.5, 4.6, 5.0, 5.5, 6.0, 6.5, 7.0		Hex or non-hex/ 2.5 Hex	Wide (Regular)	Ø3.89, 4.28, 4.78, 5.28, 6.28	Ø3.9, 4.0, 4.4, 4.5, 4.9, 5.5, 5.9
2.	Healing Abutment	Ø4.3, 4.8		Hex or non-hex/ 2.1 Hex	Narrow (mini)	Ø3.25, 3.89	Ø3.0, 3.5
		Ø4.0, 4.3, 4.5, 4.6, 4.8, 5.3, 5.5, 5.6, 6.3, 6.5, 7.3, 7.5, 8.3, 8.5		Hex or non-hex/ 2.5 Hex	Wide (Regular)	Ø3.89, 4.28, 4.78, 5.28, 6.28	Ø3.9, 4.0, 4.4, 4.5, 4.9, 5.5, 5.9
3.	Abutment Screw	Ø2.22		-	Narrow (mini)	-	-
		Ø2.1, 2.3, 2.32, 2.5		-	Wide (Regular)	-	-

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

<Substantial Equivalence to Predicate device Table – TDS (TECHWIN DENTAL SYSTEM)>

	SUBJECT Device	Primary PREDICATE Device (K160536)	Significant Difference
Manufacturer	**TECHWIN Co., Ltd.**	**Medimecca Co., Ltd.**	–
Trade Name	TDS (TECHWIN DENTAL SYSTEM)	Chaorum Implant System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	–
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	No difference.
Product Code	NHA	NHA	No difference.
Class	II	II	No difference.
Indications	The TDS (TECHWIN DENTAL SYSTEM) are prefabricated prosthetic components for direct connection to endosseous dental implants and are intended to be used as an aid in prosthetic rehabilitation. It is intended for use in edentulous and partially edentulous patients with	Chaorum Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	Similarities

	SUBJECT Device	**Primary PREDICATE Device (K160536)**	**Significant Difference**
	established bone and completed growth period to support single unit prosthetic restorations in the mandible or maxilla. It is intended for one-stage and two-stage surgical procedures. This system is intended for delayed loading.	Chaorum Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	
Dual Abutment			
Design	 [Hex/Non-hex O-type]  [Hex/Non-hex D-type]  [Hex I-type]	 [Hex/Non-hex]	Similarities
Diameter (ø)	**[Hex/Non-hex O-type]** : 4.0, 4.6, 5.0, 6.0, 7.0 mm **[Hex/Non-hex D-type]** : 4.5, 5.5, 6.5 mm **[Hex I-type]** : 4.5, 5.5 mm	3.5, 4.0, 4.5, 5.5, 5.5, 6.0, 6.5 mm	Similarities
Post Height	4.0, 5.5, 7.0 mm	4.5, 5.5, 7.0 mm	Similarities
Gingival Height	**[Hex/Non-hex O-type]** **:** 1.0, 1.8, 2.8, 3.8, 4.8 mm **[Hex/Non-hex D-type]** **:** 1.0, 1.3, 2.3, 3.3, 4.3, 5.3 mm **[Hex I-type]** : 1.0, 1.8, 2.8, 3.8, 4.8 mm	0.85, 1.35, 2.35, 3.35, 4.35, 5.35 mm	Similarities
Raw material	Ti-6Al-4V ELI Titanium Alloy	Titanium Grade 4	Similarities
Connection Interface	Hex, Non-hex	Hex, Non-hex	No difference
Surface Treatment	TiN Coating	TiN Coating	No difference.
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	No difference.
Single Use/Reuse	Single use Only	Single use Only	No difference.

	SUBJECT Device	**Primary PREDICATE Device (K160536)**	**Significant Difference**
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.
SE	The subject device has a similar intended use, material, and design as the predicate device, with only minor differences in dimensions. While the subject device is indicated for single-unit loading only, as opposed to single and multiple-unit loading for the predicate device, this represents a more conservative approach that doesn't introduce additional risks. The abutment gingival height range of the subject device falls within the range of the predicate device, and the minor differences in diameter and post height are intended to meet individual patient needs without compromising performance or safety. The 4.0 mm minimum abutment post height of the subject device, compared to the 4.5 mm of the predicate device, allows for greater flexibility to accommodate patient-specific anatomical variations without affecting safety or effectiveness. Although the subject device uses Ti-6Al-4V ELI titanium alloy instead of titanium grade 4 used in the predicate, both materials are well-established in dental implant applications, with Ti-6Al-4V ELI offering improved mechanical properties and biocompatibility. The connection interface remains the same between the devices. These differences do not raise any new safety or effectiveness issues, maintaining substantial equivalence between the subject and predicate devices.		
Healing Abutment			
Design	 [O-type]  [D-type]  [I-type]	 [O-type]	Similarities
Diameter (ø)	**[O-type]** : 4.3, 4.8, 5.3, 6.3, 7.3, 8.3 mm **[D-type]** : 4.0, 4.5, 5.5, 6.5, 7.5, 8.5 mm **[I-type]** : 4.6, 5.6 mm	3.5 ~ 8.5 mm	Similarities
Post Height	**[O-type]** : 3.0, 4.0, 5.0, 7.0 mm **[D-type]** : 2.0, 3.5, 5.0, 7.0 mm **[I-type]**	2.0 ~ 7.0 mm	Similarities

	SUBJECT Device	**Primary PREDICATE Device (K160536)**	**Significant Difference**
	: 4.0, 5.5, 7.0 mm		
Gingival Height	**[O-type]** : 1.0, 2.0, 3.0, 5.0 mm **[D, I-type]** : 2.0, 3.0, 4.0 mm	0.0 ~ 5.5 mm	Similarities
Raw material	Ti-6Al-4V ELI Titanium Alloy	Titanium Grade 4	Similarities
Surface Treatment	Non/TiN Coating	TiN Coating	Similarities
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	No difference.
Single Use/Reuse	Single use Only	Single use Only	No difference.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.
SE	The subject device has a similar intended use, material, and design as the predicate device, with only minor differences in dimensions. The abutment post height and gingival height range of the subject device fall within the range of the predicate device. While there are minor differences in diameter, these variations are intended to meet individual patient needs and do not compromise performance or safety due to their minimal nature. The subject device uses Ti-6Al-4V ELI titanium alloy, whereas the predicate uses titanium grade 4. Both materials are well-established in dental implant applications, with Ti-6Al-4V ELI offering improved mechanical properties and biocompatibility. This material difference maintains substantial equivalence without raising new safety or efficacy concerns. Additionally, the subject device offers both non-coated and TiN-coated options for the Healing Abutment, while the predicate device uses only TiN coating. This flexibility in surface treatment allows for customization based on specific clinical needs without compromising the device's overall performance or biocompatibility. Furthermore, the connection interface remains the same between the devices. These minor variations do not introduce any new issues in performance or safety, thus maintaining substantial equivalence between the subject and predicate devices.		
Abutment Screw			
Design	<Abutment Screw>  [O-type]  [D-type]  [N-type]	<Abutment Screw> 	Similarities

	SUBJECT Device	**Primary PREDICATE Device (K160536)**	**Significant Difference**
	 [LA-type]  [TA-type]  [MR-type]  [MO-type]		
Diameter (ø)	**<Abutment Screw>** **[O-type]** : 2.22, 2.32 mm **[D, N, TA, MO-type]** : 2.3 mm **[LA-type]** : 2.5 mm **[MR-type]** **:** 2.1 mm	2.3 mm	Similarities
Total Length	**<Abutment Screw>** **[O-type]**: 8.35, 10.2 mm **[D -type]**: 10.2 mm **[N-type]**: 8.8 mm **[LA-type]**: 8.5 mm **[TA-type]**: 9.8 mm **[MR-type]**: 8.0 mm **[MO-type]**: 10.1 mm	9.7 ~ 11.3 mm	Similarities
Raw material	Ti-6Al-4V ELI Titanium Alloy	Titanium Grade 4	Similarities
Connection Interface	Internal Conical Connection	Internal Conical Connection	No difference.
Surface Treatment	Machined	Machined	No difference.
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	No difference.
Single Use/Reuse	Single use Only	Single use Only	No difference.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.

	SUBJECT Device	Primary PREDICATE Device (K160536)	Significant Difference
SE	The subject device has a similar intended use, material, and design as the predicate device, with only minor differences in dimensions. The range of diameter and total length of the subject device are designed to meet individual patient needs and do not raise any performance or safety issues due to the minimal nature of these size differences. While the subject device uses Ti-6Al-4V ELI titanium alloy and the predicate uses titanium grade 4, both materials are well-established in dental implant applications. Ti-6Al-4V ELI offers improved mechanical properties and biocompatibility, maintaining substantial equivalence without introducing new safety or efficacy concerns. Furthermore, the connection interface remains the same between the devices. These minor variations in dimensions and material do not compromise the device's performance or safety, thus maintaining substantial equivalence between the subject and predicate devices.		

IX. NONCLINICAL TEST

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility

Biocompatibility classification is based on the FDA Guidance Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.”

The subject devices are classified as an implant medical device, tissue/bone, long-term exposure (>30 days).

The subject devices have fulfilled all testing required by ISO 7405:2018, “Dentistry – Evaluation of biocompatibility of medical devices used in dentistry”, ISO 10993-1:2018, “Biological evaluation of medical devices – Part 1: Evaluation and testing” and the FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Cytotoxicity testing according to ISO 10993-5:2009 “Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity”, irritation testing according to ISO 10993-10:2010 and ISO 10993-23:2021, and implantation testing according to ISO 10993-6:2016 was performed to demonstrate the subject device is substantially equivalent to the predicate device (K160536).

Surface treatment

Surface treatment analysis was conducted in-house for the TDS (TECHWIN DENTAL SYSTEM). This included chemical composition analysis, scanning electron microscopy analysis, surface roughness measurements, coating thickness and porosity evaluation, mean volume percent of voids calculation, and abrasion characteristics assessment.

Sterilization

The non-sterile abutments used in the surgery must be sterilized by the end user, prior to use, as specified in the IFU. User moist heat sterilization validation for the subject non-sterile devices was conducted according to, ISO 17665-1:2006, "Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices", and ISO/TS 17665-2:2009, "Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1" and demonstrated a SAL of 10^{-6}.

A non-clinical worst-case MRI review was performed to evaluate the subject device components in the MRI environment using scientific rationale and published literature (e.g., *Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795*), based on the entire system including all variations (all compatible implant bodies, abutments) and material composition. The rationale addressed parameters according to the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque.

Reverse engineering analysis

Reverse engineering was performed to ensure compatibility with third-party implants. This process involved precise measurements of implant-abutment interfaces, tolerances, and connection geometries. Reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws was performed to ensure compatibility with third-party implants.

X. CLINICAL TESTS

This 510(k) does not include data from clinical tests.

XI. CONCLUSIONS

The above information supports that the TDS (TECHWIN DENTAL SYSTEM) is as safe and effective as the predicate device. Although there are minor design differences between the device under subject device and the predicate device, the review supports that these differences do not raise new questions of safety and effectiveness. Therefore, it is concluded that the TDS (TECHWIN DENTAL SYSTEM) is substantially equivalent to the predicate device.