February 10, 2026

Creodent Hudson Valley
Calvin Shim
Vice President
1769 Rt 52
Fishkill, New York 12524

Re: K251515
Trade/Device Name: Solidex® Ti-Links and Screws
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: May 2, 2025
Received: January 9, 2026

Dear Calvin Shim:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K251515

Device Name
Solidex® Ti-Links and Screws

Indications for Use *(Describe)*

Solidex® Ti-Links and Screws is intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Solidex® Ti-Links is to be sent to a CREODENT HUDSON VALLEY validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter(mm)	510(k) Number
Straumann Bone Level	3.3	2.8 (NC)	K083550
	4.1, 4.8	3.3 (RC)	K121131
Megagen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5	K122231

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(K251515)

This 510(k) Summary is being submitted in accordance with requirement of 21 CFR 807.92.

Submitter :

CREODENT HUDSON VALLEY

1769 Rt 52 Fishkill, NY 12524, USA

Phone : +1.845.562.1555

Official Correspondent :

CREODENT HUDSON VALLEY / Calvin Shim

1769 Rt 52 Fishkill, NY 12524, USA

Phone : +1.845.562.1555

Device Information :

Device Name : Solidex® Ti-Links and Screws

Common Name : abutment, implant, dental, endosseous

Regulation Name : Endosseous dental implant abutment

Classification : II

Primary Product Code : NHA

Secondary Product Code : PNP

Regulation Number : 872.3630

Date Prepared : Feb 10, 2026

Predicate Device

• K240982, Terrats Medical SL, DESS Dental Smart Solutions

Device Description

Solidex® Ti-Links & Screws consists of a two-piece abutment, where the titanium base will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment. The system also includes a Solidex® Screw for fixation to the implant body. Solidex® Ti-Link are made of titanium alloy conforming to ASTM F136 standard specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and are provided in various prosthetic platform diameters. Solidex® Screw is composed of titanium alloy per ASTM F136.

Solidex® Ti-Links & Screws is designed for fabrication of a patient-specific CAD/CAM zirconia superstructure on which a crown may be placed. There are two-piece abutments for which the second part (or top half) is the zirconia superstructure. They also may be used for support of a crown directly on the Ti-Link. CAD/CAM zirconia superstructure fabrication for Ti-Link is by prescription on the order of the clinician.

Solidex® Ti-Links & Screws all zirconia superstructures for use with the subject device Ti-Link will be manufactured using a digital dentistry workflow, either at a Validated Milling Center (VMC) or at the Point of Care (POC), by using scan files from intra-oral and lab (desktop) scanners, CAD/CAM software, ceramic material, and associated tooling and accessories. The digital dentistry workflow uses scan files from intra-oral and lab (desktop) scanners, CAD/CAM software, ceramic material, and associated tooling and accessories. The digital workflow includes the following products :

• Ceramic material : Sagemax NexxZr T (K130991)

• Cement : Panavia SA cement Universal (K183537)

• Desktop scanner : 3Shape E series Lab Scanner (510(k) exempt under 21 CFR 872.3661)

• Design software : 3Shape Abutment Designer Software (K151455)

• Milling machine : PrograMill PM7 (510(k) exempt under 21 CFR 872.3661)

• Milling software : PrograMill CAM (510(k) exempt under 21 CFR 872.3661)

• Digital Library / Templates (3 Shape) : The Solidex® Ti-Link CAD/CAM System shall only be used with the official "Solidex® Ti-Link Digital Library" and templates identified. The library is imported into the 3Shape software, and the design restriction parameters (minimum wall thickness, post height, maximum gingival height, etc.) are automatically applied.

The official "Solidex® Ti-Link Digital Library" can be obtained from CREODENT HUDSON VALLEY by contacting support email (inquiry@creodental.com) or from CREODENT HUDSON VALLEY web-site.

When imported into the 3Shape software, the design restriction parameters (minimum wall thickness, post height, maximum gingival height, etc.) and built-in protection features ("stops" and restriction shells) are automatically applied.

The design parameters for the CAD/CAM zirconia superstructure to be used Solidex® Ti-Links & Screws:

• Minimum wall thickness : 0.5 mm

• Minimum abutment post height : 6.0 mm

(Note)

: The abutment post height is the dimension above the gingival height.

: Feature maximum abutment post height are based on patient anatomy and clinician discretion.

• Minimum gingival height : 0.5 mm

• Maximum gingival height : 6.0 mm

• Minimum Angulation : 0°

• Maximum Angulation : 20°

The zirconia superstructure must be cemented to the Solidex® Ti-Links using Panavia SA cement Universal in a dental laboratory. Solidex® Ti-Links & Screws is provided non-sterile therefore must be sterilized after the cementation of the zirconia superstructure on Solidex® Ti-Links. Solidex® Screws are designed to attach the abutment to the implant.

Indications for Use

Solidex® Ti-Links and Screws is intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Solidex® Ti-Links is to be sent to a CREODENT HUDSON VALLEY validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter(mm)	510(k) Number
Straumann Bone Level	3.3	2.8 (NC)	K083550
	4.1, 4.8	3.3 (RC)	K121131
Megagen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5	K122231

Substantial Equivalence

[Predicate device]

K240982, Terrats Medical SL, DESS Dental Smart Solutions

[Substantial equivalence summary]

The subject device is substantially equivalent in indications and design principles to the predicate device listed above. Provided at the end of this summary is a table comparing the Indications for Use and the technological characteristics of the subject device and the predicate device.

The indications for use for the subject device is idential to that of the predicate device except for wording regarding product name and the validated milling center name. The differences in the indications for use between the subject and predicate device do not substantively alter their meaning.

The design (Abutment Designs, Prosthesis Attachment, Restoration, Platform Size, and Abutment Angle) is substantially equivalent to that of predicate device.

The material of Ti-Links, Screw, and Material of Zirconia Superstructure is substantially equivalent to that of predicate device. Regarding surface treatment, the predicate device is surface-treated, whereas the subject device is not surface-treated and is made of a material that conforms to the ASTM F136 standard (Ti-6Al-4V ELI).

The manufacturing and digital design workflow for subject device is identical to that of predicate device.

Digital manufacturing workflow of the subject device and predicate device are similar. The difference is in the manufacturer of the equipment and software used. The differences in the digital manufacturing workflow between the subject and predicate device do not affect the determination of substantial equivalence.

Since the features of the subject device are substantially equivalent to the above-mentioned devices, any minor differences in certain features compared to the predicate device are insignificant and do not affect the determination of substantial equivalence.

[Comparison between Subject and Predicate Device]

FEATURE	Subject device	Predicate device	Comparison Discussion
510(k) Number	K251515	K240982	*Not applicable*
Company Name	CREODENT HUDSON VALLEY	Terrats Medical SL	*Not applicable*
Trade Name	Solidex® Ti-Links and Screws	DESS Dental Smart Solutions	*Not applicable*
Product Code	NHA, PNP	NHA, PNP	Identical
Reason for Predicate Device	*Not applicable*	Intended Use, Indications for Use, Design (Abutment Designs, Prosthesis Attachment, Restoration, Platform Size, Abutment Angle), Material (Material for Ti-Links, Surface Treatment for Ti-Links, Material for Screw, Surface Treatment for Screw, Material for Zirconia Superstructure), Manufacturing(Manufacturing, Digital Design Workflow, Digital Manufacturing Workflow)	*Not applicable*
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Identical
Indications for Use	Solidex® Ti-Links and Screws is intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with Solidex® Ti-Links is to be sent to a CREODENT HUDSON VALLEY validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.	This indications for use of the subject and predicate device are similar The indications for use of the subject and predicate device have slight differences in wording, for clarification only. For the subject and predicate device, there is a difference only in the product name and the validated milling center name. The differences in the indications for use

FEATURE	Subject device	Predicate device	Comparison Discussion
			between the subject and predicate device do not substantively alter their meaning.
Design			
Abutment Designs	CAD/CAM Bases	CAD/CAM Bases, CAD/CAM Blanks	Similar
Prosthesis Attachment	Cement-retained, Screw re-tained	Cement-retained, Screw re-tained	Identical
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Identical
Platform Size	Ø2.8mm – Ø5.7mm	Ø2.52mm – Ø6.5mm	Platform size is covered by predicate device.
Angulation of base component	0° for Ti-Links	Max 30° for Blanks, 0° for TiBases	Similar
Angulation of the final two piece abutment (base and top half combined)	Max 20°	Max 30°(for Pre-milled Blanks), 0° (straight only for Ti bases configurations)	Similar
Material			
Material of Ti-Links	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Identical
Surface Treatment of Ti-Links	Machined	Anodization and a SelectGrip® surface	The subject device is not surface-treated and is made of material conforming to ASTM F136 standard (Ti-6Al-4V ELI).
Material of Screw	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Identical
Surface Treatment of Screw	Machined	DLC Coating	The subject device is not surface-treated and is made of material conforming to ASTM F136 standard (Ti-6Al-4V ELI).
Material of Zirconia Superstructure	Zirconium Oxide (Y-TZP), K130991	Zirconium Oxide (Y-TZP), K180703	Similar (510(k) Clearance)
Manufacturing			
Manufacturing	Digital Dentistry Workflow & Validated Milling Center	Digital Dentistry Workflow & Validated Milling Center	Similar
Digital Design Workflow	• 3Shape Intraoral Scanner Trios series • 3Shape E-series Lab Scanner • 3Shape Abutment Designer Software(3Shape A/S, K151455)	• 3Shape Intraoral Scanner Trios series • 3Shape E-series and D/R2000 Lab Scanner • 3Shape Abutment Designer Software(3Shape A/S, K151455)	Similar
Digital Manufacturing Workflow	PrograMill Dry By Ivoclar with PrograMill CAM	VHF R5 By vhf camfacture AG with DentalCAM & DentalCNC	Digital Manufacturing Workflow of the subject and predicate device are similar. The difference is in

FEATURE	Subject device	Predicate device	Comparison Discussion
			the manufacturer of the equipment and software used. The differences in the digital manufacturing workflow between the subject and predicate device do not affect the determination of substantial equivalence.

Non-clinical test data

The following tests were performed for the subject device :

• Biocompatibility testing in accordance with ISO 10993-1:2018 : Cytotoxicity(Elution, MTT) in accordance with ISO 10993-5:2009

• User moist heat sterilization validation in accordance with ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020, ISO 17665:2024, ISO 11138-1:2017, ISO 11138-3:2017, ISO 11737-1:2018/Amd 1:2021, ISO 11737-2:2019, and ISO 11140-3:2007

• Mechanical testing(fatigue test) in accordance with ISO 14801:2016

• Software verification included testing of restrictions that prevent design of components outside of the stated design parameters. In addition, the abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified by the user.

• Reverse engineering analysis was conducted on OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility with the 3rd party implant systems.

• MR Compatibility Statement : A non-clinical worst-case MRI review was performed to evaluate the subject device 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). This MRI review was leveraged for the subject device.

The results of the non-clinical testing confirm that the subject device meets the criteria of the applicable standards and is substantially equivalent to the predicate device.

No clinical data were included in this submission.

Conclusion

Based on the information provided in this premarket notification, CREODENT HUDSON VALLEY concludes that the Solidex® Ti-Links and Screws is substantially equivalent to the above-mentioned currently cleared devices.

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