December 16, 2020

CreoDent Prosthetics, Ltd.
Calvin Shim
Managing Director
29 West 30th Street, 11th Floor
New York, New York 10001

Re: K202095
Trade/Device Name: CreoDent Solidex® Customized Abutment and Screw
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 11, 2020
Received: November 16, 2020

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number _K202095__

Device Name: CreoDent Solidex® Customized Abutment and Screw

Indication for Use:

The CreoDent Solidex® Customized Abutment and Screw is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant.

The CreoDent Solidex® Customized Abutment and Screw are compatible with the following:

- Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5

Prescription Use___X____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
K202095
CreoDent Prosthetics, Ltd.
Solidex® Customized Abutment and Screw

Submitter Information

Company Name:	CreoDent Prosthetics, Ltd.
Company Address:	29 West 30th Street, 11th Floor New York, New York 10001
Company Telephone:	(212) 302-3860
Company Fax:	(212) 302-3865
Contact Person:	Calvin Shim (212) 302-3860
Date Summary Prepared:	December 3, 2020

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	CreoDent Solidex® Customized Abutment and Screw
Common Name:	Endosseous Dental Implant Abutment, 21 CFR 872.3630
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INDICATIONS FOR USE

The CreoDent Solidex® Customized Abutment and Screw is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant.

The CreoDent Solidex® Customized Abutment and Screw are compatible with the following:

- Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5

DEVICE DESCRIPTION

The Solidex® Customized Abutment and Screw is Ti-6A1-4V Eli titanium alloy meets ASTM F-136 standard and is designed to be screw retained for use with endosseous dental implants to provide support for a prosthetic restoration. These abutments are indicated for cement or screw retained restorations. Solidex® Customized Abutment and Screw are compatible with:

- Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5

The design of subject device is customized to the requirements of each patient as may be specified by the prescribing dentist. Customization is limited by the minimum and maximum dimensions for wall thickness, diameter, height, collar height and angulation.

Straumann Tissue Level Standard Plus	**RN 3.3mm**		**WN 6.5mm**	
Max Diameter	5mm from Implant Axis		5mm from Implant Axis	
Min Wall thickness	.68mm		.68mm	
	Max	Min	Max	Min
Height	10mm	5mm	10mm	5mm
Collar Height	5mm	1mm	5mm	1mm
Post Height	9mm	4mm	9mm	4mm
Degree of Angulation	20	0	20	0

CAD/CAM Work Flow

The Solidex® Customized Abutment and Screw is CAD/CAM Patient Specific machine manufactured per prescription received from a dentist. The dentist will specify the implant type and size. Upon receiving the prescription from the dentist, CreoDent will only manufacture Solidex® Customized Abutment and Screw for which they have received FDA 510K clearance. Safe guards and limitation in the design software will be imposed according to specified design limitations built into abutment designer. Abutment blanks for each implant platform are produced to CreoDent Prosthetics, Ltd. specifications in Ti-6A1-4V Eli titanium alloy and Screw is CP TI Gr4 supplied by T.Strong INC, a Korean company located at 403, 433-8, Jangan-dong, Dongdeamun-gu, Seoul 130-100, Republic of Korea. T.Strong.INC obtains the abutment blank and screw materials from suppliers in the USA. All abutment blanks have prefabricated interfaces. CreoDent custom mills the non-interface portion of the abutment.

T.Strong INC obtains titanium alloy and c.p. titanium from US suppliers and mills the abutment-to-implant connection platform according to the design specifications provided by CreoDent Prosthetics, Ltd. CreoDent Prosthetics finalizes the abutment device, according to a prescription provided by a dentist at the registered and listed CreoDent manufacturing facility in New York.

EQUIVALENCE TO MARKETED DEVICE

The **CreoDent Solidex® Customized Abutments** are substantially equivalent in intended use, material, design and performance to:

- CreoDent Solidex Customized Abutments (K150012) Primary Predicate
- Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5 (K171784)

Conclusion:

The **CreoDent Solidex® Customized Abutment** and Screw are substantially equivalent to the identified predicate products noted in this 510K Summary.

Table #1 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw**	**PRIMARY Predicate Device for claimed equivalence: CreoDent Solidex Customized Abutment (K150012)**
Material	Abutment and Screw are Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard.	Abutment is Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard. It is a higher grade material with more tensile strength. The Screw is CP TI Gr4 meets ASTM F67 Standard.
Performance Characteristics	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.
Indications for Use	The CreoDent Solidex® Customized Abutment and Screw is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely endentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment and Screw are compatible with the following: • Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5	The CreoDent Solidex® Customized Abutment is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely edentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment is compatible with the following: • Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4mm, 5mm, 6mm

		• Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm
Dimensions and Angulations	CreoDent Solidex Customized Abutment and Screw sizes for • Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5 Angles not to exceed up to 20 degrees from the implant axis.	CreoDent Solidex Customized Abutment sizes for Biomet 3i Osseotite Certain 3.25mm, 4.0mm, 5.0mm and 6.0mm diameter implants. Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm Angles not to exceed up to 20 degrees from the implant axis.

Substantial Equivalence discussion difference: The differences between the subject device and the Primary predicate is the compatible implant bodies. This comparison is for similarity of device not for implant compatibility.

Table #2 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw**	**Reference Predicate Device for claimed equivalence: Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5 (K171784)**
Material	Abutment and Screw are Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard.	Abutment and Screw are Ti-6Al-7Nb titanium alloy(TAN)
Performance Characteristics	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.
Indications for Use	The CreoDent Solidex® Customized Abutment and Screw is intended for use with an endosseous implant to support a prosthetic device in patients who are partially or completely endentulous. The device can be used for single or multiple-unit restorations. The prosthesis can be cemented or screw retained to the abutment. An abutment screw is used to secure the abutment to the endosseous implant. The CreoDent Solidex® Customized Abutment and Screw are compatible with the following: • Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5	Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures. Titanium Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations

Dimensions and Angulations	CreoDent Solidex Customized Abutment and Screw sizes for • Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5 Angles not to exceed up to 20 degrees from the implant axis.	Straumann Abutment sizes for Straumann Tissue Level Implants RN 3.3mm and WN 6.5mm Angles not to exceed up to 30 degrees from the implant axis.

Substantial Equivalence discussion differences: The only difference between the subject device and the reference predicate is the maximum angulation. Solidex Customized abutments have a less extreme maximum angulation. The difference is also mitigated by fatigue testing and reverse engineering dimensional analysis.

The CreoDent Solidex® Customized Abutment is compatible with the following:

Compatible Device	Implant Diameters	Implant Lengths
Straumann Tissue Level Standard Plus	RN 3.3mm	6 mm 8 mm 10 mm 12 mm 14 mm
	WN 6.5mm	6 mm 8 mm 10 mm 12 mm

Non-clinical Testing Data: Static/Fatigue testing was conducted in accordance with ISO 14801:2007E Dentistry-Implants-Dynamic fatigue test for endosseous dental implants with the worst case scenario for the Solidex® Customized Abutment and Screw connection platform. Reverse engineering dimensional analysis was conducted using OEM implant bodies, OEM abutments and OEM abutment screws. Sterilization validation was conducted according to ISO 17665-1 was performed. These results demonstrated that the Solidex® Customized Abutment and Screw have sufficient mechanical strength for their intended clinical application and are compatible with Straumann Tissue Level Standard Plus RN 3.3 and WN 6.5 for which they are intended. Biocompatibility information is leveraged from our previous 510k (K150012).

CONCLUSION:

Solidex Customized Abutments incorporates the same material, similar indications for use, dimension, design, abutment seat, screw seat, anatomical site, connection, type of retention and technological characteristics as the predicate device (K150012). Both the subject and predicate device share the same intended use. The only significant difference between the devices is the implant platform compatibility which has been mitigated through dynamic fatigue testing and 3rd party compatibility testing. The Solidex Customized abutments are substantially equivalent to the predicate (K150012).