December 2, 2022

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

Re: K220390
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: October 19, 2022
Received: October 21, 2022

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 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

Indications for Use

510(k) Number (if known): K220390

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. CreoDent Solidex Customized Abutments and Screws to be compatible with the Implant Direct InterActive/Swish Active 3.0mm implants are only indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

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

510(k)	Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)
K163194	Neodent Implant Systems	GM Line	3.5/3.75	3.5/3.75
K143011	Implant Direct Sybron Manufacturing LLC	2014 InterActive/SwishActive System	3.0	3.0

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)

K220390
510(k) Summary
CreoDent Prosthetics, Ltd.
11/22/2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	CreoDent Prosthetics, Ltd. 29 West 30th Street, 11th Floor New York, New York 10001 Telephone: +1 212-302-3860
Official Contact	Calvin Shim – Managing Director
Email	calvin.shim@creodental.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	CreoDent Solidex® Customized Abutment and Screw
Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Code:	Class II
Product Code:	NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1B)

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. CreoDent Solidex Customized Abutments and Screws to be compatible with the Implant Direct InterActive/Swish Active 3.0mm implants are only indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The CreoDent Solidex® Customized Abutment is compatible with the following dental implants:

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K163194	Neodent Implant Systems	GM Line	3.5/3.75	3.5/3.75
K143011	Implant Direct Sybron Manufacturing LLC	2014 InterActive/SwishActive System	3.0	3.0

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:

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)	Max Diameter	Wall Thickness (mm)	Height Min/Max (mm)	Post Height Min/Max (mm)	Collar Height Min/Max (mm)	Angulation Min/Max (Degress)
Neodent Implant Systems	GM Line	3.5/3.75	3.5/3.75	5mm from Implant Axis	.68	5 - 10	4 - 9	1 - 5	0 - 20

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)	Max Diameter	Wall Thickness (mm)	Height Min/Max (mm)	Post Height Min/Max (mm)	Collar Height Min/Max (mm)	Angulation Min/Max (Degress)
Implant Direct Sybron Manufacturing LLC	2014 InterActive/SwishActive System	3.0	3.0	5mm from Implant Axis	.68	5 - 10	4 - 9	1 - 5	0 - 20

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.

CAD/CAM Workflow

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. Prescriptions can be submitted by mailing physical submissions to our office, or digital submissions can be uploaded to our online client portal. All submissions are entered under the client's specific accounts for record keeping and case tracking. Safeguards 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 Subject device is substantially equivalent in indications and design principles to the predicate devices shown above. Below are summary tables comparing the technological characteristics and the Indications for Use of the subject device abutments and the predicate device abutments.

Table 1A: Indications for Use Comparison with Predicate K150012

<table>
<tr><th>Subject Devices
CreoDent Solidex® Customized Abutment</th><th>Predicate Devices
CreoDent Solidex® Customized Abutment
K150012</th></tr>
<tr><td>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 endosseous implant. CreoDent Solidex Customized Abutments and Screws to be compatible with the Implant Direct InterActive/Swish Active 3.0mm implants are only indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

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

<table>
<tr><th>Manufacturer</th><th>Implant Line</th><th>Platform Diameter (mm)</th><th>Implant Body Diameter (mm)</th></tr>
<tr><td>Neodent Implant Systems</td><td>GM Line</td><td>3.5/3.75</td><td>3.5/3.75</td></tr>
<tr><td>Implant Direct Sybron Manufacturing LLC</td><td>2014 InterActive/SwishActive System</td><td>3.0</td><td>3.0</td></tr>
</table>
</td><td>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 is compatible with the following dental implants:

<table>
<tr><th>Manufacturer</th><th>Implant Line</th><th>Platform Diameter (mm)</th><th>Implant Body Diameter (mm)</th></tr>
<tr><td>Implant Innovations</td><td>3i Osseotite Certain Dental Implants</td><td>3.25mm
4.0mm
5.0mm
6.0mm</td><td>3.25mm
4.0mm
5.0mm
6.0mm</td></tr>
<tr><td>Institut Straumann AG</td><td>Straumann Bone Level Implants</td><td>3.3mm
4.1mm
4.8mm</td><td>3.3mm
4.1mm
4.8mm</td></tr>
</table>
</td></tr>
</table>

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 Neodent GM Line and Implant Direct InterActive/SwishActive System for which they are intended.

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 1B: Indications for Use Comparison with Reference Devices

<table>
<tr>
<th>Subject Devices
CreoDent Solidex® Customized Abutment</th>
<th>Reference Device
Neodent Implant System
K163194</th>
<th>Refer Device
Implant Direct - 2014 InterActive/SwishActive System
K143011</th>
</tr>
<tr>
<td>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 restorations. The prosthesis can be cemented or screw-retained to the abutment. An abutment screw is used to secure the abutment to endosseous implant. CreoDent Solidex Customized Abutments and Screws to be compatible with the Implant Direct InterActive/Swish Active 3.0mm implants are only indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The CreoDent Solidex® Customized Abutment is compatible with the following dental implants:
<table>
<tr><th>Manufacturer</th><th>Implant Line</th><th>Platform Diameter (mm)</th><th>Implant Body Diameter (mm)</th></tr>
<tr><td>Neodent Implant Systems</td><td>GM Line</td><td>3.5/3.75</td><td>3.5/3.75</td></tr>
<tr><td>Implant Direct Sybron Manufacturing LLC</td><td>2014 InterActive/SwishActive System</td><td>3.0</td><td>3.0</td></tr>
</table>
</td>
<td>GM Exact Click Universal Abutments are intermediary prosthetic components to be installed onto GM implants to support the final prosthesis. They provided in an anti-rotational shape for the coupling with the prothesis and in various angulation, prosthetic and gingival heights to match the variation in mucosal thickness. They are indicated for cemented-retained single-tooth prostheses onto implants.

Compatibility to:
<table>
<tr><th>Manufacturer</th><th>Implant Line</th><th>Platform Diameter (mm)</th><th>Implant Body Diameter (mm)</th></tr>
<tr><td>Neodent Implant Systems</td><td>GM Line</td><td>3.5/3.75</td><td>3.5/3.75</td></tr>
</table>
</td>
<td>GPS abutments are used in attachment-retained, tissue supported restorations where the patient is fully or partially edentulous in the arch to be restored. These abutments are sold non-sterile with an accompanying Instruction for Use that provides clinicians with pre-use sterilization instructions. These abutments are made form Titanium 6AL-4V ELI with coronal region having a Titanium Nitride (TiN) coating. The TiN coating process was validated through cytotoxicity testing in accordance with ISO 10993-5.

The Straight GPS abutments are a one-piece design secured to the implant having identical interface features as the previously cleared InterActive Ball Abutments.

Compatibility to:
<table>
<tr><th>Manufacturer</th><th>Implant Line</th><th>Platform Diameter (mm)</th><th>Implant Body Diameter (mm)</th></tr>
<tr><td>Implant Direct Sybron Manufacturing LLC</td><td>2014 InterActive/SwishActive System</td><td>3.0</td><td>3.0</td></tr>
</table>
</td>
</tr>
</table>

Substantial Equivalence discussion differences: The only difference between the subject device and the reference predicate is the reference predicate is a stock abutment unable to be customized, while the CreoDent Solidex® Customized Abutment 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. Both Subject and Reference devices are compatible to the same implant system.

Technical Characteristics Substantial Equivalence Comparison Table

Parameter	**Subject Devices** CreoDent Solidex® Customized Abutment	**Predicate Devices** CreoDent Solidex® Customized Abutment K150012	**Reference Device** Neodent Implant System - GM Line K163194	**Reference Device** Implant Direct - 2014 InterActive/SwishActive System K143011	**Substantial Equivalence**
Product Code	NHA	NHA	NHA	NHA	**Substantially Equivalence**
Regulation Number	872.3630	872.3630	872.3640	872.3640	**Substantially Equivalence**
Regulatory Class	Class II	Class II	Class II	Class II	**Substantially Equivalence**
Abutment Material	Ti-6AL-4V ELI (Grade 23)	Ti-6AL-4V ELI (Grade 23)	Ti-6AL-4V ELI (Grade 23)	Titanium Alloy	**Substantially Equivalence** To Predicate and Reference devices.
Screw Material	Ti-6AL-4V ELI (Grade 23)	Ti-6AL-4V ELI (Grade 23)	Ti-6AL-4V ELI (Grade 23)	Titanium Alloy	**Substantially Equivalence** To Predicate and Reference devices.
Method Operation	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	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.	**Substantially Equivalence**
Compatible Implant Systems – Implant Diameter (mm)	Neodent GM 3.5/3.75mm Implant Direct InterActive/Swish Active 3.0mm	Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4mm, 5mm, 6mm Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm	Neodent GM 3.5/3.75mm	Implant Direct InterActive/Swish Analog 3.0mm	**Substantially Equivalence** By means of combing Predicate and Reference device compatible implant systems

Substantial Equivalence discussion differences: The only difference between the subject device and the reference predicate is the reference predicate is a stock abutment unable to be customized, while the CreoDent Solidex® Customized Abutment 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. Both Subject and Reference devices are compatible to the same implant system.

CLINICAL TESTING
No clinical data is included in this submission.

NON-CLINICAL PERFORMANCE TESTING
Static/Fatigue testing was conducted in accordance with ISO 14801:2007 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants with the worst-case scenario for the CreoDent Solidex® Customized Abutment and Screw connection platform. Reverse engineering dimensional analysis using OEM compatible implant bodies, abutments, and abutment fixation screws. Sterilization validation according to ISO 17665-1 was performed. These results demonstrated that the CreoDent Solidex® Customized Abutment and Screw have sufficient mechanical strength for their intended clinical application.

The Solidex® Customized Abutment and Screw are Ti-6A1-4V Eli titanium alloy and meets ASTM F-136 Standard. These grades of materials have a common use in surgical implants. Further evaluation for potential cytotoxic effects conducted in accordance with ISO 10993-5, Biological evaluation of medical devices – Part 5:Test for in vitro cytotoxicity showed no evidence of causing cell lysis or toxicity. Therefore, we believe there are no special biocompatibility data requirements.

Non-clinical worst-case MRI review was performed to evaluate the metallic CreoDent Solidex® Customized Abutment and Screw devices 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, 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.

CONCLUSION
Overall, the Subject device has the following similarities to the legally marketed Predicate and Reference devices: They have nearly the same Indications of Use. They have the same Intended Use. The have the same Technological Characteristics.

Overall, the Subject device and Predicate devices have been demonstrated to be Substantially Equivalent.