DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

July 18, 2017

Re: K170100
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: June 14, 2017
Received: June 20, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -A

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K170100

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 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:

- Sweden & Martina Premium Implant System 3.3mm and 3.8mm

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

CreoDent Prosthetics, Ltd.
Solidex® Customized Abutment and Screw

Submitter Information

Company Name:	CreoDent Prosthetics, Ltd.
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Date Summary Prepared:	Oct 1, 2016

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 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:

- Sweden & Martina Premium Implant System 3.3mm and 3.8mm

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:

- Sweden & Martina Premium Implant System 3.3mm and 3.8mm

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.

EQUIVALENCE TO MARKETED DEVICE

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

- Creodent Solidex Customlized Abutments (K150012) Primary Predicate
- Sweden & Martina Premium Implant System (K142242)

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	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.	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: • Sweden & Martina Premium Implant System 3.3mm and 3.8mm	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 • Sweden & Martina Premium Implant System 3.3mm and 3.8mm 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.

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 the Sweden & Martina Premium Implant for which they are intended. Biocompatibility information is leveraged from our previous 510k (K150012).

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: Sweden & Martina Premium Abutments** (K142242)

Material	Abutment and Screw are Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard.	-Abutment and Screw: Same Titanium Alloy
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.	The prosthetics can be cemented, screw retained or friction fir to the abutment.
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: • Sweden & Martina Premium Implant System 3.3mm and 3.8mm	The Premium abutments is intended for us with an endossous implant to support a prosthetic device in partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthetic device in the mandible or maxilla. The prosthetics can be cemented, screw retained or friction fir to the abutment.
Dimensions and Angulations	Creodent Solidex Customized Abutment and Screw sizes for • Sweden & Martina Premium Implant System 3.3mm and 3.8mm Angles not to exceed up to 20 degrees from the implant axis.	Sweden & Martina Premium Implant System 3.3mm and 3.8mm Stock abutments

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 the Sweden & Martina Premium Implant for which they are intended. Biocompatibility information is leveraged from our previous 510k (K150012).

Substantial Equivalence discussion differences: The only difference between the subject device and the reference predicate is that one is a stock abutment and Solidex is a Customized abutment. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis.

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

Compatible Device	Implant Diameters	Implant Lengths
Sweden & Martina Premium Implant	3.3mm	10mm 11.5mm 13mm 15mm
	3.8mm	6mm 7mm 8.5mm 8.5mm 10mm 11.5mm 13mm 15mm

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).