K113738

510(k) Summary

CreoDent Prosthetics, Ltd.
Solidex® Customized Abutment

SEP 17 2013

Submitter Information

Company Name:	CreoDent Prosthetics, Ltd.
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Date Summary Prepared:	July 27, 2012

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	CreoDent Solidex® Customized Abutment
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 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 is compatible with the following:

- Nobel Replace™ TiUnite Endosseous 3.5mm, 4.3mm, and 5.0mm diameter Implants
- Nobel Active™ Internal Connection 3.5mm and 4.3mm diameter Implants
- Zimmer Screw-Vent 3.7mm, 4.7mm ; Zimmer Tapered Screw-Vent , 3.7mm, 4.7mm and 6.0mm diameter Implants

DEVICE DESCRIPTION

The Solidex® Customized Abutment is made of CP TI Gr4 grade unalloyed titanium for surgical implants applications (meets ASTM Standard F67/Gr 04-06) 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 Abutments are compatible with:

- Nobel Replace™ TiUnite Endosseous 3.5mm, 4.3mm, and 5.0mm diameter Implants (510K#023113)
- Nobel Active™ Internal Connection 3.5mm and 4.3mm diameter Implants (510K#071370)
- Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered Screw-Vent 3.7mm, 4.7mm and 6.0mm diameter Implants (510K#013227)

The design of subject device is customized to the requirements of each patient as may be specified by the prescribing dentist.

EQUIVALENCE TO MARKETED DEVICE

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

- Nobel TDS Abutment for Nobel Biocare Replace and Abutment Screw 510K#091026
- Nobel Procera Ti Abutment and Abutment Screw 510K#091756
- Zimmer Patient-Specific Abutment, Internal Hex Titanium and Abutment Screw 510K#071439

Conclusion:

The **Creodent Solidex® Customized Abutments** 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 K#113738**	**Predicate Device for claimed equivalence: Nobel TDS Abutment for Nobel Biocare Replace and Abutment Screw 510K#091026**
Material	-Abutment: CP Ti Gr4 unalloyed titanium for surgical implants applications meets ASTM F67/Gr 04-06 Standard -Abutment Screw: Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard	-Abutment: Comparable Titanium alloy -Abutment Screw: Comparable 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.	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 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: • Nobel Replace™ TiUnite Endosseous 3.5mm, 4.3mm, and 5.0mm diameter Implants • Nobel Active™ Internal Connection 3.5mm and 4.3mm diameter Implants • Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered Screw-Vent 3.7mm, 4.7mm and 6.0mm diameter Implants	TDS Abutment for Nobel Biocare Replace is intended for use with dental implants as support for single or multiple tooth prosthesis in the maxilla or mandible of a partially or fully edentulous patient.
Dimensions and Angulations	Abutment sizes for Nobel Replace™ TiUnite Endosseous 3.5mm (NP), 4.3mm (RP), and 5.0mm (WP) diameter implants. Angles not to exceed up to 20 degrees from	Abutment sizes for Nobel Replace™ TiUnite Endosseous 3.5mm (NP), 4.3mm (RP), and 5.0mm (WP) diameter implants. Angles not to exceed up to 30 degrees

	the implant axis.	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 connection platform. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Nobel Replace™ TiUnite Endosseous implant system for which they are intended.

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

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw K#113738**	**Predicate Device for claimed equivalence: Nobel Procera Ti Abutment and Abutment Screw 510K#091756**
Material	-Abutment: CP Ti Gr4 unalloyed titanium for surgical implants applications meets ASTM F67/Gr 04-06 Standard -Abutment Screw: Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard	-Abutment: Comparable Titanium alloy -Abutment Screw: Comparable 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.	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 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: • Nobel Replace™ TiUnite Endosseous 3.5mm, 4.3mm, and 5.0mm diameter Implants • Nobel Active™ Internal Connection 3.5mm and 4.3mm diameter Implants • Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered Screw-Vent 3.7mm, 4.7mm and 6.0mm diameter Implants	The NobelProcera Ti Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.
Dimensions and Angulations	Abutment sizes for Nobel Active™ Internal Connection 3.5mm (NP) and 4.3mm (RP) diameter implants. Angles not to exceed up to 20 degrees	Abutment sizes for Nobel Active™ Internal Connection 3.5mm (NP) and 4.3mm (RP) diameter implants.

	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 connection platform. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Nobel Active™ Internal Connection implant system for which they are intended.

Table #3 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	**CreoDent Solidex® Customized Abutment and Abutment Screw K#113738**	**Predicate Device for claimed equivalence: Zimmer Patient-Specific Abutment, Internal Hex Titanium and Abutment Screw 510K#071439**
Material	-Abutment: CP Ti Gr4 unalloyed titanium for surgical implants applications meets ASTM F67/Gr 04-06 Standard -Abutment Screw: Ti-6A1-4V Eli titanium alloy meets ASTM F-136 Standard	-Abutment: Comparable Titanium alloy -Abutment Screw: Comparable 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.	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 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: • Nobel Replace™ TiUnite Endosseous 3.5mm, 4.3mm, and 5.0mm diameter Implants • Nobel Active™ Internal Connection 3.5mm and 4.3mm diameter Implants • Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered Screw-Vent 3.7mm, 4.7mm and 6.0mm diameter Implants.	The Zimmer® Patient-Specific Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.
Dimensions and	Abutment sizes for the Zimmer Screw-Vent 3.7mm, 4.7mm; Zimmer Tapered	Abutment sizes for the Zimmer Tapered Screw-Vent T, Tapered Screw-Vent P

Angulations	Screw-Vent 3.7mm (NP), 4.7mm (RP) and 6.0mm diameter implants. Angles not to exceed up to 20 degrees from the implant axis.	3.7mm (NP), 4.7mm (RP) and 6.0mm diameter implants. Angles not to exceed up to 30 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 connection platform. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Zimmer Tapered Screw-Vent implant system for which they are intended.

Table #4 Legally marketed predicate device (Implant) to which compatibility is claimed for the Solidex® Customized Abutment:

Compatible Device	Implant Diameters	Implant Lengths
Nobel Replace™ TiUnite Endosseous Implant 510K#023113	3.5mm 3.5mm 3.5mm 3.5mm	10.0mm 13.0mm 16.0mm
Nobel Replace™ TiUnite Endosseous Implant 510K#023113	4.3mm 4.3mm	10.0mm 13.0mm
Nobel Replace™ TiUnite Endosseous Implant 510K#023113	5.0mm 5.0mm	10.0mm 13.0mm

Table #5 Legally marketed predicate device (Implant) to which compatibility for the Solidex® Customized Abutment:

Compatible Device	Implant Diameters	Implant Lengths
Nobel Active™ Internal Connection Implant 510K#071370	3.5mm 3.5mm 3.5mm 3.5mm	10.0mm 11.5mm 13.0mm 15.0mm
Nobel Active™ Internal Connection Implant 510K#071370	4.3mm 4.3mm 4.3mm 4.3mm	10.0mm 11.5mm 13.0mm 15.0mm

Table #6 Legally marketed predicate device (Implant) to which compatibility for the Solidex® Customized Abutment:

Compatible Device	Implant Diameters	Implant Lengths
Zimmer Screw-Vent , Tapered Screw-Vent Implant 510K#013227	3.7mm	8.0mm – 16.0mm
Zimmer Screw-Vent , Tapered Screw-Vent Implant 510K#013227	4.7mm	8.0mm – 16.0mm
Zimmer Tapered Screw-Vent Implant 510K#013227	6.0mm	8.0mm – 16.0mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SEP 1 7 2013

CreoDental Prosthetics, Limited
Mr. Calvin Shim
Managing Director
29 West 30th Street, 11th floor
NEW YORK NY 10001

Re: K113738
Trade/Device Name: CreoDent Solidex® Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 9, 2013
Received: September 11, 2013

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113738

Indications for Use

510(k) Number (if known) K113738

Device Name: CreoDent Solidex® Customized Abutment

Indication for Use:

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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)

Andrew I. Steen -S
2013.09.17 14:33:09 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113738