



Food and Drug Administration
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September 29, 2016

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

Re: K160436

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: August 31, 2016
Received: September 2, 2016

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 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" (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 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,

 Tina Kiang
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Tina Kiang, Ph.D.
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) K160436

Device Name: CreoDent Solidex® Customized Abutment

Indication 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:

- Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm
- Hiossen TS Implants 3.5mm, 4.0mm

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-the-Counter Use _____
(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

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: August 31, 2016

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 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:

- Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm
- Hiossen TS Implants 3.5mm, 4.0mm

DEVICE DESCRIPTION

The Solidex® Customized Abutment is Ti-6Al-4V Eli titanium alloy meets ASTM F-136 Standard and Screw is CP TI Gr4 meets ASTM F67 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:

- Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm (K024111)
- Hiossen TS Implants 3.5mm, 4.0mm (K151858)

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:

- Primary Predicate Creodent Solidex Customized Abutments (150012)
- Reference Predicate Astra Tech Implant Systems (K091239)
- Reference Predicate Hiossen ET Smart Fit Abutment (K123627)

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	<u>PRIMARY</u> Predicate Device for claimed equivalence: Creodent Solidex Customized Abutment (K150012)
Material	Abutment is Ti-6Al-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.	Abutment is Ti-6Al-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	<p>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.</p> <p>The CreoDent Solidex® Customized Abutment is compatible with the following:</p> <ul style="list-style-type: none"> • Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm • Hiossen TS Implants 3.5mm, 4.0mm 	<p>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.</p> <p>The CreoDent Solidex® Customized Abutment is compatible with the following:</p> <ul style="list-style-type: none"> • Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4mm, 5mm, 6mm • Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm
Dimensions and Angulations	<p>Creodent Solidex Customized Abutment sizes for</p> <ul style="list-style-type: none"> • Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm • Hiossen TS Implants 3.5mm, 4.0mm <p>Angles not to exceed up to 20 degrees from the implant axis.</p>	<p>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</p> <p>Angles not to exceed up to 20 degrees from the implant axis.</p>

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. Reverse engineering dimensional analysis using compatible implant fixtures and sterilization validation according to ISO 17665-1 was performed. These results demonstrated that the

Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Astra Tech Osseospeed Tx and Hiossen TS implant system for which they are intended.

Substantial Equivalence discussion Differences: The difference between the subject device and the Primary predicate is the compatible implant bodies. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis, and identification of reference predicate for compatible implant bodies.

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: Astra Tech Systems (K091239)
Material	Abutment is Ti-6Al-4V Eli titanium alloy meets ASTM F-136 Standard and Screw is CP TI Gr4 meets ASTM F67 Standard	-Abutment and 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.	Astra Tech Implant system implants, abutments, prosthetic components and accessories are intended for supporting prosthetic devices in edentulous or partially edentulous patients to restore esthetics and chewing function.
Indications for Use	<p>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.</p> <p>The CreoDent Solidex® Customized Abutment is compatible with the following:</p> <ul style="list-style-type: none"> • Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm 	Astra Tech Implant System is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. The device may be used equally well in a single-stage or two-stage surgical procedure. It is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations.
Dimensions and Angulations	<ul style="list-style-type: none"> • Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm <p>Angles not to exceed up to 20 degrees from the implant axis.</p>	<ul style="list-style-type: none"> • Astra Tech Osseospeed Implants 3.0mm, 3.5mm, 4.0mm 4.5mm, 5.0mm

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. Reverse engineering dimensional analysis using compatible implant fixtures and sterilization validation according to ISO 17665-1 was performed. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Astra Tech Osseospeed Tx Dental implant system for which they are intended.

Substantial Equivalence Discussion Differences: The difference between the subject device and the reference predicate is the patient specific option of customizing the shape of the abutment. The Reference Predicate is only stock abutments. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis.

Table #3 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: Hiossen ET Smart Fit Abutment (K123627)
Material	Abutment is Ti-6Al-4V Eli titanium alloy meets ASTM F-136 Standard and Screw is CP TI Gr4 meets ASTM F67 Standard	-Abutment and Screw: Comparable Titanium
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	<p>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.</p> <p>The CreoDent Solidex® Customized Abutment is compatible with the following:</p> <ul style="list-style-type: none"> • Hiossen TS Implants 3.5mm, 4.0mm 	ET SmartFit Abutment is intended for use with a dental implant to provide support for prosthetic restoration such as crowns, bridges, or overdentures.
Dimensions and Angulations	<p>Solidex Abutment sizes for</p> <ul style="list-style-type: none"> • Hiossen TS Implants 3.5mm, 4.0mm <p>Angles not to exceed up to 20 degrees from the implant axis.</p>	<ul style="list-style-type: none"> • Hiossen TS Implants 3.5mm, 4.0mm <p>Angles not to exceed up to 30 degrees from the implant axis.</p>

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. Reverse engineering dimensional analysis using compatible implant fixtures and sterilization validation according to ISO 17665-1 was performed. These results demonstrated that the Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Hiossen TS implant system for which they are intended.

Substantial Equivalence Discussion Differences: The difference between the subject device and the reference predicate is the angulation. This difference is mitigated by fatigue testing, reverse engineering dimensional analysis.

Table #3 Legally marketed predicate device (Implant) to which compatibility is claimed for the Solidex® Customized Abutment:

Compatible Device	Implant Diameters	Implant Lengths
Astra Tech Osseospeed TX (K024111)	3.5mm 3.5mm 3.5mm 3.5mm 3.5mm	8mm 9mm 11mm 13mm 15mm 17mm
Astra Tech Osseospeed TX. (K024111)	4.5mm 4.5mm 4.5mm 4.5mm 4.5mm	9mm 11mm 13mm 15mm 17mm

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

Compatible Device	Implant Diameters	Implant Lengths
Hiossen TS Implants (K151858)	3.5mm 3.5mm 3.5mm 3.5mm	8.5mm 10.0mm 11.5mm 13mm
Hiossen TS Implants (K151858)	4.0mm 4.0mm 4.0mm 4.0mm	8.5mm 10.0mm 11.5mm 13mm

CONCLUSION:

Solidex Customized Abutments incorporates the same material, same indications for use, dimension, design, abutment seat, screw seat, anatomical site, connection, type of retention and technological characteristics as the predicate device. Both the subject and predicate device share the same intended use, namely to serve as an aid in prosthetic reconstructions, such as crowns and bridges Also both the predicate and subject devices are intended to be milled into patient specific abutments using CAD/CAM technology. The only difference is the implant platform which has been validated through fatigue testing. There aren't any further variations between

the two devices which would anyway impede the substantially equivalent decision. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.

Conclusion The Solidex Customized abutments constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, Solidex Customized abutments and its predicate are substantially equivalent.