



Food and Drug Administration
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May 8, 2017

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

Re: K162734

Trade/Device Name: CreoDent Solidex® Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 24, 2017
Received: March 9, 2017

Dear Mr. 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" (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,

Michael J. Ryan -S

for 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 K162734

Device Name: CreoDent Solidex® Customized Abutment

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 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 Solidex Abutment is compatible with the following dental implants:

Manufacturer	Implant Line	Platform Diameter (mm)	Body Diameter (mm)	Lengths (mm)
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	3.3	3.3	11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	3.8	3.8	9,11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	4.3	3.8	9,11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	5	4.3	9,11,13,16
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	2.8	8,9.5,11,12.5,14,17
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4	3.5	8,9.5,11,12.5,14
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.2	3.5	8,9.5,11,12.5,14,17
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5	4.3	8,9.5,11,12.5,14
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6	5.3	8,9.5,11,12.5
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4	8,10,12,14
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4	10,11.5,13,15
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7	10,11.5,13,15
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3	8,10,11.5,13

All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.

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

K162734

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: May 8, 2017

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 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 the endosseous implant.

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

Manufacturer	Implant Line	Platform Diameter (mm)	Body Diameter (mm)	Lengths (mm)
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	3.3	3.3	11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	3.8	3.8	9,11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	4.3	3.8	9,11,13,16

Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	5	4.3	9,11,13,16
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	2.8	8,9.5,11,12.5,14,17
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4	3.5	8,9.5,11,12.5,14
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.2	3.5	8,9.5,11,12.5,14,17
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5	4.3	8,9.5,11,12.5,14
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6	5.3	8,9.5,11,12.5
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4	8,10,12,14
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4	10,11.5,13,15
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7	10,11.5,13,15
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3	8,10,11.5,13

All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.

DEVICE DESCRIPTION

The Solidex® Customized Abutment and Screw is Ti-6Al-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 Abutments are compatible with:

Manufacturer	Implant Line	Platform Diameter (mm)	Body Diameter (mm)	Lengths (mm)
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	3.3	3.3	11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	3.8	3.8	9,11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	4.3	3.8	9,11,13,16
Altatec Biotechnologies N.A. incorporated	Camlog Screwline Implant Promote	5	4.3	9,11,13,16
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	2.8	8,9.5,11,12.5,14,17
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4	3.5	8,9.5,11,12.5,14
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.2	3.5	8,9.5,11,12.5,14,17

Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5	4.3	8,9.5,11,12.5,14
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6	5.3	8,9.5,11,12.5
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4	8,10,12,14
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4	10,11.5,13,15
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7	10,11.5,13,15
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3	8,10,11.5,13

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, post height, collar height and angulation.

EQUIVALENCE TO MARKETING DEVICE

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

Primary Predicate:

Creodent Solidex® Customized Abutments (K150012)

Reference Predicates:

- Inclusive Titanium Abutments for Camlog (K121391)
- Atlantis Abutment for Keystone Implants (K103020)
- Dentium Implantium and Superline Abutments (K141457)
- Milling Abutment for CAD/CAM Dental Abutments (K151984)

Compatible Implant Systems Clearance numbers:

- Camlog Screwline Implant System (K022425)
- SPI ELEMENT dental Implants (K030689)
- Denitum Co., Ltd Implantium (K041368)
- PrimaConnex Internal Connection Implant System (K051614)

Comparison to the Predicates

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 #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 and Screw are Ti-6Al-4V Eli titanium alloy meets ASTM F-136 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	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: • Camlog Screwline Implant Promte: 3.3mm, 3.8mm, 4.3mm, 5.0mm • SPI Element Dental Implants RC INCELL(Thommen): 3.5mm, 4.0mm, 4.2mm, 5.0mm, 6.0mm • Dentium Co., Ltd Implantium: 3.6mm • Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone): 3.5mm, 4.1mm, 5.0mm All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.	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 sizes for • Camlog Screwline Implant Promte: 3.3mm, 3.8mm, 4.3mm, 5.0mm	Creodent Solidex Customized Abutment sizes for Biomet 3i Osseotite Certain 3.25mm, 4.0mm, 5.0mm and 6.0mm diameter implants.

	- SPI Element Dental Implants RC INCELL(Thommen): 3.5mm, 4.0mm, 4.2mm, 5.0mm, 6.0mm - Dentium Co., Ltd Implantium: 3.6mm - Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone): 3.5mm, 4.1mm, 5.0mm Angles not to exceed up to 20 degrees from the implant axis.	Straumann Bone Level implants 3.3mm, 4.1mm, 4.8mm Angles not to exceed up to 20 degrees from the implant axis.
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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 OEM compatible implant bodies, abutments, and abutment fixation screws. 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.

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	<u>Reference Predicate Device for claimed equivalence: Atlantis Abutment for Camlog (K022425)</u>
Material	Abutment and Screw are Ti-6Al-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.	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: Camlog Screwline Implant Promte: 3.3mm, 3.8mm, 4.3mm, 5.0mm	Altatec Biotechnologies implants are indicated for single tooth replacement, as immediate abutments on long span to bridgework, as distal abutments on free-end edentulous areas to be restored with fixed bridgework, to support overdentures in total or partially edentulous arches, and as abutments supporting a full arch fixed prosthesis in the totally edentulous mandible or maxilla.

	All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.	
Dimensions and Angulations	Camlog Screwline Implant Promte: 3.3mm, 3.8mm, 4.3mm, 5.0mm Angles not to exceed up to 20 degrees from the implant axis.	Camlog Screwline Implant System: 3.3mm, 3.8mm, 4.3mm, 5.0mm, 6.0mm 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. 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 Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the Camlog Screwline Implant system for which they are intended.

Substantial Equivalence discussion differences: The only 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 (Abutment) to which equivalence is claimed:

Technological Characteristics	CreoDent Solidex® Customized Abutment and Abutment Screw	<u>Reference Predicate Device for claimed equivalence: Thommen Milling Abutments for CAD/CAM (K151984)</u>
Material	Abutment and Screw are Ti-6Al-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.	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	Thommen Milling abutments for CAD/CAM are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges, and over dentures. All digitally designed abutments for use with Thommen Milling abutments

	endosseous implant. The CreoDent Solidex® Customized Abutment is compatible with the following: SPI Element Dental Implants RC INCELL(Thommen): 3.5mm, 4.0mm, 4.2mm, 5.0mm, 6.0mm All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.	for CAD/CAM are intended to be sent to a Thommen validated milling center for manufacture.
Dimensions and Angulations	Solidex Abutment sizes for SPI Element Dental Implants RC INCELL(Thommen): 3.5mm, 4.0mm, 4.2mm, 5.0mm, 6.0mm Angles not to exceed up to 20 degrees from the implant axis.	Thommen SPI Implants 3.5mm, 4.0mm, 4.5mm, 5.0mm, 6.0mm 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. 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 Solidex® customized Abutment have sufficient mechanical strength for their intended clinical application and are compatible with the SPI Element Dental Implant (Thommen) system for which they are intended.

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

Table #4 Legally marketed predicate device (Abutment) to which equivalence is claimed:

Technological Characteristics	CreoDent Solidex® Customized Abutment and Abutment Screw	<u>Reference Predicate Device for claimed equivalence: Dentium Implantium Dental Abutments (K052823)</u>
Material	Abutment and Screw are Ti-6Al-4V Eli titanium alloy meets ASTM F-136 Standard.	-Abutment and Screw: Comparable Titanium
Performance	Allows the prosthesis to be cemented or	Allows the prosthesis to be cemented

Characteristics	screw retained to the abutment. The abutment screw is designed to secure the abutment to the endosseous implant.	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: • Dentium Co., Ltd Implantium: 3.6mm All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.	The Implantium abutments are intended to be used with Implantium root form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root for endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.
Dimensions and Angulations	Solidex Abutment sizes for • Dentium Co., Ltd Implantium: 3.6mm Angles not to exceed up to 20 degrees from the implant axis.	• Dentium Co., Ltd Implantium: 3.6mm- 4.8mm

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 OEM compatible implant bodies, abutments, and abutment fixation screws. 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 Dentium Co., Ltd Implantium system for which they are intended.

Substantial Equivalence discussion difference: The only differences between the subject device and the reference predicate is that Dentium Implantium abutments are stock abutments verse Solidex Customized Abutments.

Table #5 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: Atlantis
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		Abutment for Keystone Implant (K103020)
Material	Abutment and Screw are Ti-6Al-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.	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: Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone): 3.5mm, 4.1mm, 5.0mm All digitally designed files for Creodent Solidex Customized Abutments are to be sent back to a Creodent validated manufacturing facility for manufacture.	The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. This device is compatible with the following manufacturers' implant systems: The titanium abutments are compatible with the Keystone 3.5mm, 4.0mm, 4.1mm and 5.0mm Keystone Implants. The zirconia abutments are compatible with the Keystone 3.5mm, 4.0mm, 4.1mm and 5.0mm Keystone Implants. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments on small diameter implants are intended for the anterior region only.
Dimensions and Angulations	Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone): 3.5mm, 4.1mm, 5.0mm	Life Core Prima Connex Internal Connection Implant System (KeyStone): 3.5mm, 4.1mm, 5.0mm

	Angles not to exceed up to 20 degrees from the implant axis.	Angles not to exceed up to 30 degrees from the implant axis.
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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 OEM compatible implant bodies, abutments, and abutment fixation screws. 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 Life Core Prima Connex Internal Connection Implant System for which they are intended.

Substantial Equivalence discussion: The only difference between the subject device and the reference predicate is the angulation. 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
Camlog Screwline Implants Promote	3.3mm	11mm 13mm 16mm
Camlog Screwline Implants Promote	3.8mm	9mm 11mm 13mm 16mm
Camlog Screwline Implants Promote	4.3mm	9mm 11mm 13mm 16mm
Camlog Screwline Implants Promote	5.0mm	9mm 11mm 13mm 16mm

Compatible Device	Implant Diameters	Implant Lengths
SPI Element Dental Implants RC INCELL (Thommen)	3.5mm	8mm 9.5mm 11mm 12.5mm 14mm 17mm
SPI Element Dental Implants RC INCELL (Thommen)	4.0mm	8mm 9.5mm 11mm 12.5mm 14mm
SPI Element Dental Implants RC	4.2mm	8mm 9.5mm

INCELL (Thommen)		11mm 12.5mm 14mm 17mm
SPI Element Dental Implants RC INCELL (Thommen)	5.0mm	8mm 9.5mm 11mm 12.5mm 14mm
SPI Element Dental Implants RC INCELL (Thommen)	6.0mm	8mm 9.5mm 11mm 12.5mm

Compatible Device	Implant Diameters	Implant Lengths
Dentium Co., Ltd Implantium:	3.6mm	8mm 10mm 12mm 14mm

Compatible Device	Implant Diameters	Implant Lengths
Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone)	3.5mm	10mm 11.5mm 13mm 15mm
Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone)	4.1mm	10mm 11.5mm 13mm 15mm
Life Core Prima Connex Internal Connection Implant System Tapered (KeyStone)	5.0mm	8mm 10mm 11.5mm 13mm

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. 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 and reverse engineering dimensional analysis. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate. The Solidex Customized abutments constitute 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.