4/2/2021

CreoDent Prosthetics, Ltd.
% Chris Brown, Manager
Aclivi, LLC
6455 Farley Road
Pinckney, Michigan 48169 USA

Re: K202909
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 26, 2021
Received: March 3, 2021

Dear Chris Brown:

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202909

Device Name
CreoDent Solidex® Customized Abutment

Indications for Use *(Describe)*
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 CreoDent Solidex® Customized Abutment is compatible with the following dental implants:

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.3	3.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.8	3.8
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	4.3	4.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	5.0	5.0
Astra Tech, Inc	Osseospeed TX Implants	3.5	3.5
Astra Tech, Inc	Osseospeed TX Implants	4.5	4.5
Biomet	3i Osseotite Certain Dental Implants	3.4	3.25
Biomet	3i Osseotite Certain Dental Implants	4.1	4.0
Biomet	3i Osseotite Certain Dental Implants	5.0	5.0
Biomet	3i Osseotite Certain Dental Implants	6.0	6.0
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4
Hiossen	Hiossen TS Implants	3.5 (Mini)	3.5
Hiossen	Hiossen TS Implants	4.0 (Regular)	4.0
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3
Nobel Biocare	NobelActive™ Internal Connection Implant	3.5 (NP)	3.5
Nobel Biocare	NobelActive™ Internal Connection Implant	3.9 (RP)	4.3
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	3.5 (NP)	3.5
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	4.3, 5.0 (RP)	4.3, 5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	3.5
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.0	4.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.5	4.2
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5.0	5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6.0	6.0
Straumann	Straumann Bone Level (BL) Implants	3.3 (NC)	3.3
Straumann	Straumann Bone Level (BL) Implants	4.1, 4.8 (RC)	4.1, 4.8
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	3.5	3.7
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	4.5	4.7
Zimmer	Zimmer Tapered Screw-Vent Implant	5.7	6.0

All digitally designed files for CreoDent Solidex® Customized Abutment are to be sent back to a CreoDent-validated manufacturing facility for manufacture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K202909
510(k) Summary
CreoDent Prosthetics, Ltd.
CreoDent Solidex® Customized Abutment
4/2/2021

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
Representative/Consultant	Chris Brown, BSEE Aclivi, LLC 3250 Brackley Drive Ann Arbor, Michigan 48105 Telephone: +1 (810) 360-9773 E-mail: acliviconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	CreoDent Solidex® Customized Abutment
Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Class:	Class II
Product Code:	NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device in this submission is substantially equivalent in indications, intended use and design principles to the following Predicate device.

510(k)	Predicate Device Name	Company Name
K162734	CreoDent Solidex® Customized Abutment	CreoDent Prosthetics, Ltd.

The primary intent of this submission is to expand the Predicate device clearance to also include the following legally-marketed Reference device abutments and screws within a common Indications for Use which includes the statement that "digitally designed files for CreoDent Solidex® Customized Abutment are to be sent back to a CreoDent-validated manufacturing facility for manufacture."

510(k)	Reference Device Name	Company Name
K113738	CreoDent Solidex® Customized Abutment	CreoDent Prosthetics, Ltd.
K150012	CreoDent Solidex® Customized Abutment	CreoDent Prosthetics, Ltd.
K160436	CreoDent Solidex® Customized Abutment	CreoDent Prosthetics, Ltd.

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

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.3	3.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.8	3.8
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	4.3	4.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	5.0	5.0
Astra Tech, Inc	Osseospeed TX Implants	3.5	3.5
Astra Tech, Inc	Osseospeed TX Implants	4.5	4.5
Biomet	3i Osseotite Certain Dental Implants	3.4	3.25
Biomet	3i Osseotite Certain Dental Implants	4.1	4.0
Biomet	3i Osseotite Certain Dental Implants	5.0	5.0
Biomet	3i Osseotite Certain Dental Implants	6.0	6.0
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4
Hiossen	Hiossen TS Implants	3.5 (Mini)	3.5
Hiossen	Hiossen TS Implants	4.0 (Regular)	4.0
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3
Nobel Biocare	NobelActive™ Internal Connection Implant	3.5 (NP)	3.5
Nobel Biocare	NobelActive™ Internal Connection Implant	3.9 (RP)	4.3
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	3.5 (NP)	3.5
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	4.3, 5.0 (RP)	4.3, 5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	3.5
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.0	4.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.5	4.2
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5.0	5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6.0	6.0
Straumann	Straumann Bone Level (BL) Implants	3.3 (NC)	3.3
Straumann	Straumann Bone Level (BL) Implants	4.1, 4.8 (RC)	4.1, 4.8
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	3.5	3.7
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	4.5	4.7
Zimmer	Zimmer Tapered Screw-Vent Implant	5.7	6.0

All digitally designed files for CreoDent Solidex® Customized Abutment are to be sent back to a CreoDent-validated manufacturing facility for manufacture.

DEVICE DESCRIPTION

The CreoDent Solidex® Customized Abutment is fabricated of Ti-6AL-4V ELI titanium alloy meeting the requirements of ASTM F136 or Commercially Pure (CP Ti) titanium meeting the requirements of ASTM F67 (Grade 04-06). The CreoDent Solidex® Customized Abutment retention screws are fabricated of Ti-6AL-4V ELI titanium alloy meeting the requirements of ASTM F136 or Commercially Pure (CP Ti) titanium meeting the requirements of ASTM F67 (Grade 04-06). The CreoDent Solidex® Customized Abutment is 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. CreoDent Solidex® Customized Abutments are compatible with the following implant systems and the listed implant and restorative platform diameters:

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.3	3.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.8	3.8
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	4.3	4.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	5.0	5.0
Astra Tech, Inc	Osseospeed TX Implants	3.5	3.5
Astra Tech, Inc	Osseospeed TX Implants	4.5	4.5
Biomet	3i Osseotite Certain Dental Implants	3.4	3.25
Biomet	3i Osseotite Certain Dental Implants	4.1	4.0
Biomet	3i Osseotite Certain Dental Implants	5.0	5.0
Biomet	3i Osseotite Certain Dental Implants	6.0	6.0
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4
Hiossen	Hiossen TS Implants	3.5 (Mini)	3.5
Hiossen	Hiossen TS Implants	4.0 (Regular)	4.0
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3
Nobel Biocare	NobelActive™ Internal Connection Implant	3.5 (NP)	3.5
Nobel Biocare	NobelActive™ Internal Connection Implant	3.9 (RP)	4.3
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	3.5 (NP)	3.5
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	4.3, 5.0 (RP)	4.3, 5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	3.5
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.0	4.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.2	4.5
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5.0	5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6.0	6.0
Straumann	Straumann Bone Level (BL) Implants	3.3 (NC)	3.3
Straumann	Straumann Bone Level (BL) Implants	4.1, 4.8 (RC)	4.1, 4.8
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	3.5	3.7
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	4.5	4.7
Zimmer	Zimmer Tapered Screw-Vent Implant	5.7	6.0

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. All digitally designed files for CreoDent Solidex® Customized Abutment are to be sent back to a CreoDent-validated manufacturing facility for manufacture.

This submission contains no new compatibilities.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent to the Predicate device with respect to Indications for Use and technological principles. The comparison table below compare the Indications for Use and Technological Characteristics of the Subject and Predicate devices.

Table 5A: Indications for Use Comparison with Predicate K162734

Subject Device
CreoDent Solidex® Customized Abutment

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

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.3	3.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.8	3.8
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	4.3	4.3
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	5.0	5.0
Astra Tech, Inc	Osseospeed TX Implants	3.5	3.5
Astra Tech, Inc	Osseospeed TX Implants	4.5	4.5
Biomet	3i Osseotite Certain Dental Implants	3.4	3.25
Biomet	3i Osseotite Certain Dental Implants	4.1	4.0
Biomet	3i Osseotite Certain Dental Implants	5.0	5.0
Biomet	3i Osseotite Certain Dental Implants	6.0	6.0
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4
Hiossen	Hiossen TS Implants	3.5 (Mini)	3.5
Hiossen	Hiossen TS Implants	4.0 (Regular)	4.0
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	3.5	2.4
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	4.1	2.7
Lifecore Biomedical, Inc	PrimaConnex Implants Internal (KeyStone)	5.0	3.3
Nobel Biocare	NobelActive™ Internal Connection Implant (NP)	3.5 (NP)	3.5
Nobel Biocare	NobelActive™ Internal Connection Implant (RP)	3.9 (RP)	4.3
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	3.5 (NP)	3.5
Nobel Biocare	NobelReplace™ TiUnite Endosseous Implant	4.3, 5.0 (RP)	4.3, 5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	3.5	3.5
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.0	4.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	4.5	4.2
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	5.0	5.0
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6.0	6.0
Straumann	Straumann Bone Level (BL) Implants	3.3 (NC)	3.3
Straumann	Straumann Bone Level (BL) Implants	4.1, 4.8 (RC)	4.1, 4.8
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	3.5	3.7
Zimmer	Zimmer Screw-Vent, Tapered Screw-Vent Implant	4.5	4.7
Zimmer	Zimmer Tapered Screw-Vent Implant	5.7	6.0

All digitally designed files for CreoDent Solidex® Customized Abutment are to be sent back to a CreoDent-validated manufacturing facility for manufacture.

Predicate Device
CreoDent Solidex® Customized Abutment
K162734

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® Customized Abutment is compatible with the following dental implants:

Manufacturer	Implant Line	Platform Diameter (mm)	Implant Body Diameter (mm)	Implant Lengths (mm)
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.3	3.3	11,13,16
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	3.8	3.8	9,11,13,16
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	4.3	4.3	9,11,13,16
Altatec Biotechnolgies N.A. Incorporated	Camlog Screwline Implant Promote	5.0	5.0	9,11,13,16
Dentium CO., Ltd	Dentium 3.6mm Implantium	3.6	3.4	8,10,12,14
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	4.0	3.5	8,9.5,11,12.5,14,17
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	5.0	4.3	8,9.5,11,12.5,14,17
Thommen Medical AG	SPI Element Dental Implants RC INCELL PF	6.0	5.3	8,9.5,11,12.5,14,17
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 Abutment are to be sent back to a Creodent-validated manufacturing facility for manufacture.

The Subject and Predicate devices are Substantially Equivalent, only differing in the list of compatible implant systems supporting a finding of Substantial Equivalence. The implant length column was removed from the compatibility table, as the implant and restorative platform diameters are the primary determining factors in compatibility. Differences in the list of compatible implant systems for each clearance does not change the intended use of the device.

Table 5B: Indications for Use Comparison with Reference Devices

Subject Device CreoDent Solidex® Customized Abutment	**Reference Device** CreoDent Solidex® Customized Abutment K113738	**Reference Device** CreoDent Solidex® Customized Abutment K150012	**Reference Device** CreoDent Solidex® Customized Abutment K160436
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 CreoDent Solidex® Customized Abutment is compatible with the following dental implants: ***(refer to compatibility table listed in Table 5A above)*** All digitally designed files for CreoDent Solidex® Customized Abutment 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 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® Customized Abutment is compatible with: • Nobel Replacem TiUnite Endlosseous 3.5mm, 4.3mm, and 5.0mm diameter Implants (510K#023113) • Nobel Active Internal Connection 3.5mm and 4.3mm diameter Implants(510OK#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.	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 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® Customized Abutment is compatible with the following: • Biomet 3i Osseotite Certain Dental Implants 3.25mm, 4.0mm, 5.0mm, 6.0mm • Straumann Bone Level Implants 3.3mm, 4.1mm, 4.8mm	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 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® Customized Abutment is compatible with the following: • Astra Tech Osseospeed TX Implants 3.5mm, 4.5mm • Hiossen TS Implants 3.5mm, 4.0mm

The Subject device Indications for Use statement combines the sponsor's previous clearance compatible systems into a single statement. The Subject and Reference device Indications for Use statements are highly similar, only differing in the lists of compatible implant systems and adding the statement clarifying digitally designed abutments are to be sent to a CreoDent-validated manufacturing facility for manufacture. The combined list of compatible implant systems of the Subject device does not change the intended use of the device to support a dental prosthetic device. Specifying the

manufacturing location does not change the intended use of the device. Compatible system restorative platform diameters are now included in the Subject device compatibility table for additional clarity.

Technical Characteristics Substantial Equivalence Comparison Table

Parameter	**Subject Device** CreoDent Solidex® Customized Abutment	**Predicate Device** CreoDent Solidex® Customized Abutment K162734	**Reference Device** CreoDent Solidex® Customized Abutment K113738	**Reference Device** CreoDent Solidex® Customized Abutment K150012	**Reference Device** CreoDent Solidex® Customized Abutment K160436	**Substantial Equivalence**
Product Code	NHA	NHA	NHA	NHA	NHA	***Substantially Equivalent***
Regulation Number	872.3630	872.3630	872.3630	872.3630	872.3630	***Substantially Equivalent***
Regulatory Class	Class II	Class II	Class II	Class II	Class II	***Substantially Equivalent***
Abutment Material	Ti-6AL-4V ELI (Grade 23) Camlog Screwline - 3.3,3.8,4.3,5.0 Astra Tech Osseospeed TX - 3.5, 4.5 Biomet 3i Certain - 3.25,4.0, 5.0, 6.0 Dentium 3.6 Implantium - 3.4 Hiossen TS - 3.5, 4.0 PrimaConnex (KeyStone) – 2.4,2.7,3.3 Straumann Bone Level – 3.3,4.1, 4.8 Thommen SPI Element - 3.5,4.0,4.2,5.0,6.0 CP TI (Commercially Pure Ti) NobelActive – 3.5, 4.3 NobelReplace – 3.5,4.3,5.0 Zimmer – 3.7,4.7,6.0	Ti-6AL-4V ELI (Grade 23)	CP TI (Commercially Pure Ti)	Ti-6AL-4V ELI (Grade 23)	Ti-6AL-4V ELI (Grade 23)	***Substantially Equivalent*** *– to Predicate, and K113738, K150012, and K160436 Reference devices*
Screw Material	Ti-6AL-4V ELI (Grade 23) Camlog Screwline - 3.3,3.8,4.3,5.0 Dentium 3.6 Implantium - 3.4 PrimaConnex (KeyStone) – 2.4,2.7,3.3 NobelActive – 3.5, 4.3 NobelReplace – 3.5,4.3,5.0 Thommen SPI Element - 3.5,4.0,4.2,5.0,6.0 Zimmer – 3.7,4.7,6.0 CP TI (Commercially Pure Ti) Astra Tech Osseospeed TX - 3.5, 4.5 Biomet 3i Certain - 3.25,4.0, 5.0, 6.0 Hiossen TS - 3.5, 4.0 Straumann Bone Level – 3.3,4.1,4.8	Ti-6AL-4V ELI (Grade 23)	Ti-6AL-4V ELI (Grade 23)	CP TI (Commercially Pure Ti)	CP TI (Commercially Pure Ti)	***Substantially Equivalent*** *– to Predicate, and K113738, K150012, and K160436 Reference devices*

Method of 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.	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 Equivalent***
Compatible Implant Systems - Implant Diameter (mm)	Camlog Screwline - 3.3,3.8,4.3,5.0 Astra Tech Osseospeed TX - 3.5, 4.5 Biomet 3i Certain - 3.25,4.0, 5.0, 6.0 Dentium 3.6 Implantium - 3.4 Hiossen TS - 3.5, 4.0 PrimaConnex (KeyStone) – 2.4,2.7,3.3 NobelActive – 3.5, 4.3 NobelReplace – 3.5,4.3,5.0 Straumann Bone Level – 3.3,4.1, 4.8 Thommen SPI Element - 3.5,4.0,4.2,5.0,6.0 Zimmer – 3.7,4.7,6.0	Camlog Screwline - 3.3,3.8,4.3,5.0 Ossespeed TX - 3.5, 4.5 Dentium 3.6 Implantium - 3.4 PrimaConnex (KeyStone) – 2.4,2.7,3.3 Thommen SPI Element - 3.5,4.0,4.2,5.0,6.0 (corrected from 2.8,3.5,3.5,4.3,5.3)	NobelActive – 3.5, 4.3 NobelReplace – 3.5,4.3,5.0 Zimmer – 3.7,4.7,6.0	Biomet 3i Certain - 3.25,4.0, 5.0, 6.0 Straumann Bone Level – 3.3,4.1,4.8	Astra Tech Osseospeed TX - 3.5, 4.5 Hiossen TS - 3.5, 4.0	***Substantially Equivalent –*** By means of combining Predicate and Reference device compatible implant systems

The abutment and screw material of the Reference devices are fabricated of either commercially pure titanium (CP Ti) or Ti-6AL-4V ELI (Grade 23) titanium. The materials are highly similar. Both materials are commonly used for endosseous dental implant abutments and retention screws and have been validated through performance testing. The combined list of compatible implant systems of the Subject device does not change the intended use of the device to support a dental prosthetic device.

Abutment Design Parameters (Dimensional Limitations) Comparison Table

Subject Device - CreoDent Solidex® Customized Abutment								
Implant System Ø – Restorative platform diameter	**Max Diameter (mm)**	**Min Wall Thickness (mm)**	**Min Abutment Height (mm)**	**Max Abutment Height (mm)**	**Min Collar Height (mm)**	**Max Collar Height (mm)**	**Max Post Angulation (°)**	**Source Clearance**
Camlog Screwline Implant Promote	5	0.68	5	10	1	5	20	K162734 (P)
Astra Tech Osseospeed TX	5	0.68	5	10	1	5	20	K160436 (R)
Biomet 3i Osseotite Certain Ø3.4, 4.1, 5.0 mm	5	0.68	5	10	1	5	20	K150012 (R)
Biomet 3i Osseotite Certain Ø6mm	5	0.74	5	10	1	5	20	K150012 (R)
Dentium 3.6 mm Implantium	5	0.68	5	10	1	5	20	K162734 (P)
Hiossen TS	5	0.68	5	10	1	5	20	K160436 (R)
PrimaConnex Implant Internal (KeyStone)	5	0.68	5	10	1	5	20	K162734 (P)
NobelBiocare NobelActive Internal	5	0.68	5	10	1	5	20	K113738 (R)
NobelBiocare NobelReplace TiUnite	5	0.68	5	10	1	5	20	K113738 (R)
SPI Element Dental Implants RC INCELL PF Ø3.5, 4.0, 4.5 mm	5	0.68	5	10	1	5	20	K162734 (P)
SPI Element Dental Implants RC INCELL PF Ø5.0, 6.0 mm	5	0.74	5	10	1	5	20	K162734 (P)
Straumann Bone Level	5	0.68	5	10	1	5	20	K150012 (R)
Zimmer Screw-Vent, Tapered Screw-Vent	5	0.68	5	10	1	5	20	K113738 (R)
Predicate Device - CreoDent Solidex® Customized Abutment K162734								
Implant System Ø – Restorative platform diameter	**Max Diameter (mm)**	**Min Wall Thickness (mm)**	**Min Abutment Height (mm)**	**Max Abutment Height (mm)**	**Min Collar Height (mm)**	**Max Collar Height (mm)**	**Max Post Angulation (°)**	
Camlog Screwline Implant Promote	5	0.68	5	10	1	5	20	
Dentium 3.6 mm Implantium	5	0.68	5	10	1	5	20	
PrimaConnex Implant Internal (KeyStone)	5	0.68	5	10	1	5	20	
SPI Element Dental Implants RC INCELL PF Ø3.5, 4.0, 4.5 mm	5	0.68	5	10	1	5	20	
SPI Element Dental Implants RC INCELL PF Ø5.0, 6.0 mm	5	0.74	5	10	1	5	20	
Reference Device - CreoDent Solidex® Customized Abutment K113738								
Implant System Ø – Restorative platform diameter	**Max Diameter (mm)**	**Min Wall Thickness (mm)**	**Min Abutment Height (mm)**	**Max Abutment Height (mm)**	**Min Collar Height (mm)**	**Max Collar Height (mm)**	**Max Post Angulation (°)**	
NobelBiocare NobelActive Internal	5	0.68	5	10	1	5	20	
NobelBiocare NobelReplace TiUnite	5	0.68	5	10	1	5	20	
Zimmer Screw-Vent, Tapered Screw-Vent	5	0.68	5	10	1	5	20	
Reference Device - CreoDent Solidex® Customized Abutment K150012								
Implant System Ø – Restorative platform diameter	**Max Diameter (mm)**	**Min Wall Thickness (mm)**	**Min Abutment Height (mm)**	**Max Abutment Height (mm)**	**Min Collar Height (mm)**	**Max Collar Height (mm)**	**Max Post Angulation (°)**	
Biomet 3i Osseotite Certain Ø3.4, 4.1, 5.0 mm	5	0.68	5	10	1	5	20	
Biomet 3i Osseotite Certain Ø6mm	5	0.74	5	10	1	5	20	
Straumann Bone Level	5	0.68	5	10	1	5	20	
Reference Device - CreoDent Solidex® Customized Abutment K160436								
Implant System Ø – Restorative platform diameter	**Max Diameter (mm)**	**Min Wall Thickness (mm)**	**Min Abutment Height (mm)**	**Max Abutment Height (mm)**	**Min Collar Height (mm)**	**Max Collar Height (mm)**	**Max Post Angulation (°)**	
Astra Tech Osseospeed TX	5	0.68	5	10	1	5	20	
Hiossen TS	5	0.68	5	10	1	5	20	

Note: Dimensional limitations are applicable to all compatible implant restorative platform diameters unless otherwise noted.

The individual abutment design parameters of each compatible implant system in the Subject device is identical to individual abutment design parameters of each compatible implant system within the Predicate and Reference devices supporting a finding of substantial equivalence.

Overall, the Technological Characteristics of the Subject device and that of the Predicate and Reference devices support a finding of Substantial Equivalence.

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 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 have sufficient mechanical strength for their intended clinical application.

Test results and Biological Evaluation performed for the sponsor's Predicate and Reference devices demonstrate suitable biocompatibility of the Subject device.

No new testing was performed as a part of this submission. Fatigue testing, reverse engineering, sterilization, and biocompatibility testing are all leveraged from previous submissions.

CONCLUSION

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

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