Dental Direkt GmbH
Patrick Berz
Manager Regulatory Affairs International
Industriezentrum 106-108
Spenge, 32139
GERMANY

January 11, 2023

Re: K191111
Trade/Device Name: DD Solid Connect® CAD/CAM Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 13, 2022
Received: December 15, 2022

Dear Patrick Berz:

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K191111

Device Name
DD Solid Connect® CAD/CAM Abutments

Indications for Use *(Describe)*

DD Solid Connect® CAD/CAM Abutments are used to support prosthetic restorations in combination with endosseous dental implants in the upper and/or lower jaw.

All digitally designed custom abutments for use with DD Solid Connect® CAD/CAM Abutments are to be sent to a Dental Direkt validated milling center for manufacture.

DD Prefab abutments, for the Zimmer Biomet 3i Certain 3.4mm implant bodies, and DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies, are indicated for maxillary lateral and mandibular central/lateral incisors only.

Compatible Implant Systems:

Manufacturer	Implant System	Diameter (mm)
- Altatech	Camlog	3.3, 3.8, 4.3, 5.0
- Nobel Biocare	Nobel Active	3.5, 4.3/5.0
- Nobel Biocare	Replace Select Tapered	3.5, 4.3, 5.0
- Dentsply Implants	AstraTech OsseoSpeed	3.5/4.1, 4.5/5.0
- Straumann	Bone Level	3.3, 4.1/4.8
- Straumann	SynOcta	4.8, 6.5
- Zimmer Dental	Tapered Screw-Vent	3.5, 4.5, 5.7
- Dentsply Implants	Xive	3.4, 3.8, 4.5, 5.5
- Dentsply Implants	Astra EV	3.6, 4.2, 4.8, 5.4
- Zimmer Biomet 3i	Certain	3.4, 4.1/5.0

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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510(k) Number: K191111

Date: January 11, 2023

510(k) Summary	
Submitter of 510(k)	Dental Direkt GmbH Industriezentrum 106-108 32139 Spenge / Germany
Contact Person	Patrick Berz, Manager Regulatory Affairs Phone: +49 5225 86319-42 Fax: +49 5225 86319-99 E-mail: p.berz@dentaldirekt.de
Establishment Registration Number	3008347275
Date Prepared	January 11, 2023
Trade Name of Device	*DD Solid Connect*® CAD/CAM Abutments
Common Name	Dental Abutment System
Classification Name	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Product Code	NHA
Panel	Dental
Classification	Class 2
Primary Predicate Device	K180564 Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases
Reference Devices	K202909 Creodent Prosthetics Ltd. – CreoDent Solidex® Customized Abutment K191222 Prismatik Dentalcraft, Inc. – Inclusive® Titanium Abutments
Indications for Use	*DD Solid Connect*® CAD/CAM Abutments are used to support prosthetic restorations in combination with endosseous dental implants in the upper and/or lower jaw. All digitally designed custom abutments for use with *DD Solid Connect*® CAD/CAM Abutments are to be sent to a

	Dental Direkt validated milling center for manufacture. DD Prefab abutments, for the Zimmer Biomet 3i Certain 3.4mm implant bodies, and DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies, are indicated for maxillary lateral and mandibular central/lateral incisors only. Compatible Implant Systems: - Altatech: Camlog (3.3, 3.8, 4.3, 5.0) - Nobel Biocare: Nobel Active (3.5, 4.3/5.0) - Nobel Biocare: Replace Select Tapered (3.5, 4.3, 5.0) - Dentsply Implants: Xive (3.4, 3.8, 4.5, 5.5) - Straumann: Bone Level (3.3, 4.1/4.8) - Straumann: SynOcta (4.8, 6.5) - Zimmer Dental: Tapered Screw-Vent (3.5, 4.5, 5.7) - Dentsply Implants: Astra Tech OsseoSpeed (3.5/4.0, 4.5/5.0) - Dentsply Implants: Astra EV (3.6, 4.2, 4.8, 5.4) - Zimmer Biomet 3i: Certain (3.4, 4.1/5.0)
Device Description	The *DD Solid Connect*® CAD/CAM Abutments consist of the following parts: *DD Prefab, DD Ti-Base 2CUT and DD Ti-Base 2CUT noLock*. The *DD Solid Connect* CAD/CAM Abutments are designed and made to individually fit the individual requirements for each patient**.** *DD Prefab* attach directly to the following dental implants: - Altatech: Camlog Screw-Line (3.3, 3.8, 4.3, 5.0) - Nobel Biocare: Nobel Active (3.5 NP, 4.3/5.0 RP) - Nobel Biocare: Replace Select Tapered (3.5, 4.3, 5.0) - Dentsply Implants: Astra Tech OsseoSpeed (3.5/4.0, 4.5/5.0) - Straumann: Bone Level (3.3, 4.1/4.8) - Straumann: SynOcta (4.8, 6.5) - Zimmer Dental: Tapered Screw-Vent (3.5, 4.5, 5.7) - Dentsply Implants: Xive (3.4, 3.8, 4.5, 5.5) - Dentsply Implants: Astra EV (3.6, 4.2, 4.8, 5.4) - Zimmer Biomet 3i: Certain (3.4, 4.1/5.0) *DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock* attach directly to the following dental implants: - Altatech: Camlog Screw-Line (3.3, 3.8, 4.3, 5.0)

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	The *DD Prefab* blanks are prefabricated components for the metal-cutting production of individualized and one-piece abutments using CAD/CAM technology. The Ti-Bases (*DD Ti-Base 2CUT / DD Ti-Base 2CUT no-Lock*) are used as part of a two piece abutment, where the base is premanufactured from titanium alloy (Ti-6Al-4V ELI) and the top half is a CAD-CAM zirconia super-structure, milled at a validated milling center. These pieces are cemented together to form the final abutment. All three implant components, the *DD Prefab, the DD Ti-Base 2CUT and the DD Ti-Base 2CUT noLock* are delivered each with an implant screw (DD Implant screw).
Performance data	Fatigue testing according to ISO 14801 [FDA Recognition #4-195] and FDA guidance for Industry and FDA Staff *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004. Biocompatibilty testing for cytotoxicity according to ISO 10993-5 [FDA Recognition #2-245]. Sterilization validation according to ISO 17665-1 [FDA Recognition #14-333], ISO 11737-1 [FDA Recognition #14-577] and ISO 11737-2 [FDA Recognition #14-540] Reverse engineering dimensional analysis was conducted using OEM implant bodies, OEM abutments, and OEM abutment screws.
Material	DD Prefab, DD Ti-Base 2CUT (lower part), DD Ti-Base 2CUT noLock (lower part), DD Implant screw: **Titanium Grade 5 (Ti-6Al-4V ELI)** DD Ti-Base 2CUT (upper part) and DD Ti-Base noLock (upper part): **Zirconia, ISO 13356**
Technological Characteristics	The *DD Solid Connect*® CAD/CAM Abutments are a dental system for the CAD/CAM manufacture of individual abutments. The products are made of Titanium Grade 5 ELI, which is used since a long time for dental implants and in medicine for bone and joint replacements, cardiovascular devices and surgical instruments.

DD Prefab:
The DD Prefab is used for fabricating customized abutments on implants in the upper and lower jaw for restorations with an angulation correction of max. 20° to the implant axis.

The following parameters are recommended for the design of the DD Prefab:

Parameter	Specification
Abutment Post Height	4 mm - 12.5 mm
Margin height	0.5 mm - 6 mm
Diameter	3.3 mm - 12 mm
Wall thickness	0.5 mm minimum
Angle from axis of implant	0° - 20°

DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock:
The DD Ti-Base 2CUT is used for fixation of customized crown and abutment restorations incl. an anti-rotation device for the alignment of the abutment in the vertical axis for restorations with an angulation correction of max. 20° to the implant axis.

The DD Ti-Base 2CUT noLock is used for fixation of individualized bridge and bar restorations with an angulation correction of max. 20° to the implant axis.

For the top-half made of zirconia, our own zirconia materials DD Bio Z or DD Bio ZX² (K142987) are recommended, while Multilink Hybrid Abutment Cement from Ivoclar (K130436) is recommended as dental cement for fixation.

The following parameters are recommended for the design of the zirconia superstructure for DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock:

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	<table><tr><th>Parameter</th><th>Specification</th></tr><tr><td>Abutment Post Height</td><td>4 mm - 6.5 mm</td></tr><tr><td>Margin height</td><td>0.5 mm - 6 mm</td></tr><tr><td>Diameter</td><td>2.9 mm - 5 mm</td></tr><tr><td>Wall thickness</td><td>0.5 mm minimum</td></tr><tr><td>Angle from axis of implant</td><td>0° - 20°</td></tr></table>
Use in MR Environment	Non-clinical MR review was performed to evaluate the metallic devices in the MR environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the subject device components and material composition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”.

Comparison with Predicate Device / Reference Devices

Feature	**Subject Device** *DD Solid Connect®*	**Predicate Device** *Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM Ti-Bases K180564*	**Comment (Equivalence with Predicate Device)**	**Reference Device** *CreoDent Solidex Customized Abutment K202909*	**Reference Device** *Inclusive® Titanium Abutments K191222*
510(k)	K191111	K180564	N/A	K202909	K191222
Product Code	NHA	NHA	Identical	NHA	NHA
Regulatory Class	Class II	Class II	Identical	Class II	Class II
Regulation Number	872.3630	872.3630	Identical	872.3630	872.3630
Regulation Name	Endosseous dental implant abutment	Endosseous dental implant abutment	Identical	Endosseous Dental Implant Abutment,	Endosseous Dental Implant Abutment,
Trade Name 1	*DD Prefab*	Medentika Preface	N/A	CreoDent Solidex® Customized Abutment	Inclusive® Titanium Abutments
Trade Name 2	*DD Ti-Base 2CUT*	Medentika Ti-Base	N/A	N/A	
Trade Name 3	*DD Ti-Base 2CUT no-Lock*				
Manufacturer	Dental Direkt GmbH	Medentika GmbH	N/A	CreoDent Prosthetics, Ltd.	Prismatik Dentalcraft, Inc.
Intended Use	*DD Solid Connect®* CAD/CAM Abutments are intended for automated CAD/CAM fabrication of individual dental abutments. They are available for various implant systems as they have the corresponding prefabricated implant interfaces.	Titanium base, CAD/CAM Blank to be machined provide to the patient a custom designed abutment for the prosthetic restoration	Similar	Titanium base, CAD/CAM Blank to be machined provide to the patient a custom designed abutment for the prosthetic restoration	Titanium base, CAD/CAM Blank to be machined provide to the patient a custom designed abutment for the prosthetic restoration
Indications for use	*DD Solid Connect®* CAD/CAM Abutments are used to support prosthetic restorations	Medentika Preface CAD/CAM Abutments are intended for use with dental implants as	Similar with respect to: - CAD/CAM	The CreoDent Solidex® Customized Abutment and Screw is intended	Inclusive® Titanium Abutments are premanufactured prosthetic components

Feature	**Subject Device** *DD Solid Connect®*	**Predicate Device** *Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM Ti-Bases* *K180564*	**Comment (Equivalence with Predicate Device)**	**Reference Device** *CreoDent Solidex Customized Abutment* *K202909*	**Reference Device** *Inclusive® Titanium Abutments* *K191222*
	in combination with endosseous dental implants in the upper and/or lower jaw. DD Prefab abutments, for the Zimmer Biomet 3i Certain 3.4mm implant bodies, and DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies, are indicated for maxillary lateral and mandibular central/lateral incisors only. All digitally designed custom abutments for use with DD Solid Connect® CAD/CAM Abutments are to be sent to a Dental Direkt validated milling center for manufacture.	a support for single or multiple tooth prostheses in the maxilla or mandible of a partially for fully endentulous patient. Medentika Preface is intended for use with the Straumann CARES system. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann Cares validated milling center. Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially for fully endentulous patient. Table Medentika TiBase is intended for use with	- Use with dental implants - Endosseous - Maxillary or mandibular (upper or lower jaw) - Prosthetic restaurations	for use with an endosseous implant to support a prosthetic device in patents 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: (…) All digitally designed tiles for Creodont Solides Customized Abutments are to be sent back to a Creodont validated manufacturing facility for manufacture.	connected to endosseous dental implants in the edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations. All digitally designed abutments for use with Inclusive Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture. Compatible Implant System: Dentsply Implants Astra Tech Implant System® EV.

Feature	**Subject Device** *DD Solid Connect®*	**Predicate Device** *Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM Ti-Bases K180564*	**Comment (Equivalence with Predicate Device)**	**Reference Device** *CreoDent Solidex Customized Abutment K202909*	**Reference Device** *Inclusive® Titanium Abutments K191222*
		the Straumann CARES system. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann Cares validated milling center.			
Compatible Implant Systems (implant diameter in mm)	The *DD Solid Connect®* CAD/CAM Abutments are compatible to the following 10 implant systems currently marketed:	Medentika CAD/CAM Abutments are compatible with 11 dental implant systems:	N/A	Compatibility is claimed with the following implant systems:	Compatibility is claimed with the following implant systems:
- Altatech Camlog Screw-Line	3.3, 3.8, 4.3, 5.0	C-Series	Identical to Reference Device (K202909)	3.3, 3.8, 4.3, 5.0	N/A
- Nobel Biocare Nobel Active	3.5 NP, 4.3/5.0 RP	3.5, 3.9 (4.3), 3.9 (5.0)	Identical	3.5, 3.9 (4.3)	N/A
- Nobel Biocare Replace Select Tapered	3.5, 4.3, 5.0	3.5, 4.3, 5.0, 6.0 (Nobel Biocare Replace™ Select)	Identical	N/A	N/A
- Straumann Bone Level	3.3, 4.1/4.8	3.3, 4.1, 4.8	Identical	3.3, 4.1/4.8	N/A
- Straumann SynOcta	4.8, 6.5	3.5 (NNC), 4.8, 6.5 (Straumann Standard N-Series)	Identical	N/A	N/A

Feature	**Subject Device** *DD Solid Connect®*	**Predicate Device** *Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM Ti-Bases K180564*	**Comment (Equivalence with Predicate Device)**	**Reference Device** *CreoDent Solidex Customized Abutment K202909*	**Reference Device** *Inclusive® Titanium Abutments K191222*
- Zimmer Dental Tapered Screw-Vent	3.5, 4.5, 5.7	3.5, 4.5, 5.7	Identical	3.5, 4.5, 5.7	N/A
- Dentsply Implants Xive	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5	Identical	N/A	N/A
- Dentsply Implants Astra Tech OsseoSpeed	3.5/4.0, 4.5/5.0	3.5, 4.0, 4.5, 5.0	Identical	N/A	N/A
- Zimmer Biomet 3i Certain	3.4, 4.1/5.0	3.4, 4.1, 5.0	Identical	3.4, 4.1, 5.0, 6.0	N/A
- Dentsply Implants Astra EV	3.6, 4.2, 4.8, 5.4	3.6, 4.2, 4.8, 5.4	Identical	N/A	Dentsply Implants Astra EV 3.6, 4.2, 4.8, 5.4
Implant to Abutment Connection / Interface	Precision implant / abutment interface corresponding to the implant system for which it is used	Precision implant / abutment interface corresponding to the implant system for which it is used	Identical	Precision implant / abutment interface corresponding to the implant system for which it is used	Precision implant / abutment interface corresponding to the implant system for which it is used
DD Prefab	One-piece abutment	One-piece abutment	Identical	One-piece abutment	One-piece abutment
- Post Height	4 mm - 12,5 mm	4 - 15 mm	Similar	5 mm - 10 mm	Min. 4 mm
- Gingival Height	0,5 mm - 6 mm	Max. 6 mm (Minimum not stated)	Identical (Reference Device 2)	1 mm - 5 mm	0,5 mm - 6 mm
- Diameter	3,3 mm - 12 mm	Max. 13 mm (Minimum not stated)	Similar	Max. 5 mm	Max. 9,4 mm
- Angulation correction to the implant axis	0° - 20°	0° - 21°	Identical (Reference Device 1 + 2)	0° - 20°	0° - 20°

Feature	**Subject Device** *DD Solid Connect®*	**Predicate Device** *Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM Ti-Bases K180564*	**Comment (Equivalence with Predicate Device)**	**Reference Device** *CreoDent Solidex Customized Abutment K202909*	**Reference Device** *Inclusive® Titanium Abutments K191222*
- Wall Thickness	Min. 0,5 mm	Min. 0,5 mm	Identical	Min. 0,68 mm	Not stated in 510(k)
- Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Identical	Cement-retained, Screw-retained	Cement-retained, Screw-retained
- Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	Identical	Single-unit, Multi-unit	Single-unit, Multi-unit
DD Ti-Base 2CUT / DD Ti-Base 2CUT no-Lock	Two-piece abutment	Two-piece abutment	Identical	N/A	Two-piece abutment
General parameters					
- Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Identical	N/A	Cement-retained, Screw-retained
- Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	Identical	N/A	Single-unit, Multi-unit
- Angulation correction to the implant axis	0° - 20°	0° - 21°	Similar	N/A	Straight
- Retention area	34 mm²	34 mm²	Identical	N/A	N/A
Parameters for the design of the zirconia top half					
- Prosthetic Post Height	4 mm - 6,5 mm	4 - 15 mm	Similar	N/A	4 mm - 5,5 mm
- Gingival Height	0,5 mm - 6 mm	Max. 6 mm (Minimum not stated)	Identical (Reference Device 2)	N/A	0,5 mm - 6 mm
- Diameter	2,7 mm - 7 mm	Max. 10 mm (Minimum not stated)	Similar	N/A	Not stated in 510(k)
- Wall Thickness	Min. 0,5 mm	Min. 0,5 mm	Identical	N/A	Not stated in 510(k)
	Material				
One-piece abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Identical	Ti-6AL-4V ELI	Ti-6AL-4V ELI

Feature	Subject Device *DD Solid Connect®*	Predicate Device *Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM Ti-Bases* *K180564*	Comment (Equivalence with Predicate Device)	Reference Device *CreoDent Solidex Customized Abutment* *K202909*	Reference Device *Inclusive® Titanium Abutments* *K191222*
Two-piece abutment (lower part)	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Identical	N/A	Ti-6AL-4V ELI
Two-piece abutment (upper part)	Zirconia, ISO 13356	Zirconia, ISO 13356	Identical	N/A	Zirconia, ISO 13356
Screw (fixation)	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Identical	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Sterility	Provided Non-sterile	Provided Non-sterile	Identical	Provided Non-sterile	Provided Non-sterile

Substantial Equivalence Conclusion

The product *DD Solid Connect®* CAD/CAM Abutments and its accessory is as safe and effective as the predicate device / reference devices when used as instructed by knowledgeable and trained dental personnel. The product is identical to its predicates with respect to the intended use and the indications for use. The product uses the same fundamental scientific technology compared to the predicate devices / reference devices, as it uses the same materials and same manufacturing technology.

The scientific methods to evaluate the technological characteristics can be therefore considered as acceptable and the respective data demonstrate that the product is substantially equivalent to the predicate device.

The IFU´s for the subject device is nearly identical to that of the primary predicate device (K180564) and the reference devices (K202909; K191222). The minor differences in language of the subject device and the primary predicate device / reference devices include the compatible implant systems and, therefore, do not affect the intended use. An additional difference is that the DD Prefab abutments, for the Zimmer Biomet 3i Certain 3.4mm implant bodies, and the DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies, are indicated for maxillary lateral and mandibular central/lateral incisors only. This language is included in the IFU´s to support substantial equivalence of the Zimmer Biomet 3i Certain (only DD Prefab) and Camlog Screw-Line (only DD Ti-Base 2CUT) compatibility as related to the performance bench testing provided in this submission.

Due to the points mentioned above Dental Direkt GmbH believes that the new device is substantially equivalent to the legally marketed predicate device / reference devices.