April 25, 2023

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

Re: K230218
Trade/Device Name: DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 26, 2023
Received: January 26, 2023

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230218

Device Name
DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series)

Indications for Use *(Describe)*
DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series) are used to support prosthetic restorations in combination with endosseous dental implants in the upper and/or lower jaw.

DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies, Dentsply Implants Astra Tech OsseoSpeed 3.5mm implant bodies, Dentsply Implants Xive 3.4mm implant bodies, Straumann Bone Level 3.3mm implant bodies, Zimmer Biomet 3i Certain 3.4mm implant bodies and Zimmer Dental Tapered Screw-Vent 3.5mm 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 (further DD Ti-Base 2CUT series) are to be sent to a Dental Direkt validated milling center for manufacture.
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)

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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Date: **2023/04/25**

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	April 25, 2023
Trade Name of Device	*DD Solid Connect*® CAD/CAM Abutments (further DD Ti-Base 2CUT series)
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	K191111 Dental Direkt GmbH - DD Solid Connect® CAD/CAM Abutments
Indications for Use	*DD Solid Connect*® CAD/CAM Abutments (further DD Ti-Base 2CUT series) are used to support prosthetic restorations in combination with endosseous dental implants in the upper and/or lower jaw. DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies, Dentsply Implants Astra Tech OsseoSpeed 3.5mm implant bodies, Dentsply Implants Xive 3.4mm implant bodies, Straumann Bone Level 3.3mm implant

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	bodies, Zimmer Biomet 3i Certain 3.4mm implant bodies and Zimmer Dental Tapered Screw-Vent 3.5mm 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 (further DD Ti-Base 2CUT series) are to be sent to a Dental Direkt validated milling center for manufacture. 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 (further DD Ti-Base 2CUT series) consist of the following parts: *DD Ti-Base 2CUT* and *DD Ti-Base 2CUT noLock*. The *DD Solid Connect*® CAD/CAM Abutments (further DD Ti-Base 2CUT series) are designed and made to individually fit the individual requirements for each patient**.** *DD Ti-Base 2CUT* / *DD Ti-Base 2CUT noLock* attach directly to the following dental implants: - Altatech: Camlog (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) The Ti-Bases (*DD Ti-Base 2CUT* / *DD Ti-Base 2CUT noLock*) are used as part of a two piece abutment, where the base is

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	premanufactured from titanium alloy (Ti-6Al-4V ELI) and the top half is a CAD-CAM zirconia superstructure, milled at a validated milling center. These pieces are cemented together to form the final abutment. All two implant components, 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. No new biocompatibility testing: Biocompatibilty testing for cytotoxicity according to ISO 10993-5 [FDA Recognition #2-245] leveraged from Predicate Device K191111 (worst case series). No new sterilization validation: 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] leveraged from Predicate Device K191111 (worst case series). Reverse engineering dimensional analysis was conducted using OEM implant bodies, OEM abutments, and OEM abutment screws.
Material	DD Ti-Base 2CUT (lower part), DD Ti-Base 2CUT noLock (lower part), DD Implant screw: **Titanium Grade 5 (Ti-6Al-4V ELI), conforming to ASTM F136** 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 (further DD Ti-Base 2CUT series) 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

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	replacements, cardiovascular devices and surgical instruments. 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:

Parameter	Specification
Abutment Post Height	4 mm - 6.5 mm
Margin height	0.5 mm - 6 mm
Diameter	2.9 mm - 5 mm
Wall thickness	0.5 mm minimum
Angle from axis of implant	0° - 20°

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

Feature	Subject Device *DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series)*	Predicate Device *DD Solid Connect® CAD/CAM Abutments*	Comment **(Equivalence with Predicate Device)**
510(k)	This submission (K230218)	K191111	N/A
Product Code	NHA	NHA	Identical
Regulatory Class	Class II	Class II	Identical
Regulation Number	872.3630	872.3630	Identical
Regulation Name	Endosseous dental implant abutment	Endosseous dental implant abutment	Identical
Trade Name 1	*DD Ti-Base 2CUT*	*DD Ti-Base 2CUT*	Identical
Trade Name 2	*DD Ti-Base 2CUT noLock*	*DD Ti-Base 2CUT noLock*	Identical
Trade Name 3	N/A	*DD Prefab*	N/A (not part of this submission)
Manufacturer	Dental Direkt GmbH	Dental Direkt GmbH	Identical
Intended Use	*DD Solid Connect®* CAD/CAM Abutments (further DD Ti-Base 2CUT series) 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.	*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.	Identical
Indications for use	*DD Solid Connect®* CAD/CAM Abutments (further DD Ti-Base 2CUT series) are used to support prosthetic restorations in combination with endosseous dental implants in the upper and/or lower jaw. DD Ti-Base 2CUT abutments, for the Altatech Camlog Screw-Line 3.3mm implant bodies,	*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. DD Prefab abutments, for the Zimmer Biomet 3i Certain 3.4mm implant bodies, and DD Ti-Base 2CUT abutments, for the Altatech Camlog	Identical with respect to: - CAD/CAM - Use with dental implants - Endosseous - Maxillary or mandibular (upper or lower jaw) - Prosthetic restaurations

Feature	Subject Device *DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series)*	Predicate Device *DD Solid Connect® CAD/CAM Abutments*	Comment **(Equivalence with Predicate Device)**
	Dentsply Implants Astra Tech OsseoSpeed 3.5mm implant bodies, Dentsply Implants Xive 3.4mm implant bodies, Straumann Bone Level 3.3mm implant bodies, Zimmer Biomet 3i Certain 3.4mm implant bodies and Zimmer Dental Tapered Screw-Vent 3.5mm 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 (further DD Ti-Base 2CUT series) are to be sent to a Dental Direkt validated milling center for manufacture.	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.	
Compatible Implant Systems (implant diameter in mm)			
	DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock	***DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock***	***DD Prefab***
- Altatech Camlog Screw-Line	3.3, 3.8, 4.3, 5.0	3.3, 3.8, 4.3, 5.0	3.3, 3.8, 4.3, 5.0	Identical
- Nobel Biocare Nobel Active	3.5 NP, 4.3/5.0 RP	N/A	3.5 NP, 4.3/5.0 RP	Identical
- Nobel Biocare Replace Select Tapered	3.5, 4.3, 5.0	N/A	3.5, 4.3, 5.0	Identical
- Straumann Bone Level	3.3, 4.1/4.8	N/A	3.3, 4.1/4.8	Identical

Feature	Subject Device *DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series)*	Predicate Device *DD Solid Connect® CAD/CAM Abutments*		Comment **(Equivalence with Predicate Device)**
- Straumann SynOcta	4.8, 6.5	N/A	4.8, 6.5	Identical
	DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock	**DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock**	**DD Prefab**	
- Zimmer Dental Tapered Screw-Vent	3.5, 4.5, 5.7	N/A	3.5, 4.5, 5.7	Identical
- Dentsply Implants Xive	3.4, 3.8, 4.5, 5.5	N/A	3.4, 3.8, 4.5, 5.5	Identical
- Dentsply Implants Astra Tech OsseoSpeed	3.5/4.0, 4.5/5.0	N/A	3.5/4.0, 4.5/5.0	Identical
- Zimmer Biomet 3i Certain	3.4, 4.1/5.0	N/A	3.4, 4.1/5.0	Identical
- Dentsply Implants Astra EV	3.6, 4.2, 4.8, 5.4	N/A	3.6, 4.2, 4.8, 5.4	Identical
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
Design parameters DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock				
General parameters				
- Abutment type	Two-piece abutment	Two-piece abutment		Identical
- Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained		Identical
- Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit		Identical

Feature	Subject Device *DD Solid Connect® CAD/CAM Abutments (further DD Ti-Base 2CUT series)*	Predicate Device *DD Solid Connect® CAD/CAM Abutments*	Comment **(Equivalence with Predicate Device)**
- Angulation correction to the implant axis	0° - 20°	0° - 20°	Identical
- Retention area	34 mm²	34 mm²	Identical
Parameters for the design of the zirconia top half			
- Prosthetic Post Height	4 mm - 6,5 mm	4 mm - 6,5 mm	Identical
- Gingival Height	0,5 mm - 6 mm	0,5 mm - 6 mm	Identical
- Diameter	2,7 mm - 7 mm	2,7 mm - 7 mm	Identical
- Wall Thickness	Min. 0,5 mm	Min. 0,5 mm	Identical
Material			
One-piece abutment	N/A	Ti-6Al-4V ELI	N/A (not part of this submission)
Two-piece abutment (lower part)	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Identical
Two-piece abutment (upper part)	Zirconia, ISO 13356	Zirconia, ISO 13356	Identical
Screw (fixation)	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Identical
Sterility	Provided Non-sterile	Provided Non-sterile	Identical

Substantial Equivalence Conclusion

The subject device *DD Solid Connect®* CAD/CAM Abutments (further DD Ti-Base 2CUT series) is as safe and effective as the predicate device (K191111) when used as instructed by knowledgeable and trained dental personnel. The product is nearly

identical to its predicate device with respect to the Indications for Use and identical with respect to the Intended Use. Since the product DD Prefab is not part of this submission, it is not mentioned in the Indications for Use like in the Indications for Use of the predicate device.

The minor differences in language of the subject device and the predicate device (in regard to DD Ti-Base 2CUT and DD Ti-Base 2CUT noLock) also include the compatible implant systems and, therefore, do not affect the intended use. An additional difference is that the DD Ti-Base 2CUT abutments, for the Dentsply Implants Astra Tech OsseoSpeed 3.5mm implant bodies, Dentsply Implants Xive 3.4mm implant bodies, Straumann Bone Level 3.3mm implant bodies, Zimmer Biomet 3i Certain 3.4mm implant bodies and Zimmer Dental Tapered Screw-Vent 3.5mm implant bodies, are indicated for maxillary lateral and mandibular central/lateral incisors only. This language is included in the Indications for Use to support substantial equivalence of the Dentsply Implants Astra Tech OsseoSpeed, Dentsply Implants Xive, Straumann Bone Level, Zimmer Biomet 3i Certain and Zimmer Dental Tapered Screw-Vent compatibility as related to the performance bench testing results provided in this submission. Since these series were not part of the predicate device submission in regard to DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock this additional information was not included in the Indications for Use of the predicate device.

In regard to the compatible implant systems, only the Altatech Camlog Screw-Line series is also part of the submission of the predicate device in regard to DD Ti-Base 2CUT / DD Ti-Base 2CUT noLock. However, all subject series are also included in the predicate device submission in regard to the one-piece abutment DD Prefab.

The product uses the same fundamental scientific technology compared to the predicate device, 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.