November 15, 2021

Dentsply Sirona
Courtney Clark
Senior Director of Regulatory Affairs, Corporate
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K213449
Trade/Device Name: DS Implants abutments provided with the EV connection
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 25, 2021
Received: October 26, 2021

Dear Courtney Clark:

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
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)*

K213449

Device Name
DS Implants abutments provided with the EV connection

Indications for Use *(Describe)*

DS Implants abutments provided with the EV connection are intended to be used in conjunction with implants with the EV connection in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.

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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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)*

K213449

Device Name

DS Implants abutments provided with the EV connection

Indications for Use *(Describe)*

MultiBase Abutments EV:

DS Implants abutments provided with the EV connection are intended to be used in conjunction with implants with the EV connection in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.

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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Dentsply Sirona
221 West Philadelphia Street Suite 60W
York, PA 17401

510(k) SUMMARY
DS Implants abutments with EV connection
K213449

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Primary Contact Person: Courtney Clark
Telephone Number: 248-895-4379
Fax Number: 717-849-4343

Date Prepared: November 10, 2021

2. Device Name:

- Proprietary Name: DS Implants abutments provided with the EV connection
- Classification Name: Endosseous dental implant abutment
- CFR Number: 872.3630
- Device Class: II
- Product Code: NHA

3. Predicate Devices:

The proposed devices in this bundled 510(k), which are included under the same master brand – DS (Denstply Sirona) Implants abutments with EV connection, include:

(A) Cover Screw EV, Healing Abutment EV, HealDesign EV, Temp Abutment EV, TiDesign EV, CastDesign EV, Abutment Screw EV, and

(B) MultiBase Abutment EV and its accessory components including the Multibase heal cap, MultiBase temporary cylinder, MultiBase semi-burnout cylinder, and MultiBase bridge screw.

There are two primary predicate devices identified relating to the substantial equivalence for the DS Implants abutments with EV connection, as referred to above as bundles (A) and (B):

Primary Predicate (A) Device Name	**FDA Product Code**	**510(k)**	**Company Name**
OsseoSpeed Plus	NHA	K120414	Dentsply Sirona (formerly: Astra Tech AB)
Primary Predicate (B) Device Name	**FDA Product Code**	**510(k)**	**Company Name**
Multibase Abutments EV and ATLANTIS Suprastructures	NHA	K163350	Dentsply Sirona

NOTE: The OsseoSpeed Plus K120414 clearance included the Astra Tech Implant System Plus abutments, which are currently marketed as Astra Tech Implant EV abutments. Therefore, this section will hereafter refer to the abutments cleared under OsseoSpeed Plus (K120414) as *Astra Tech Implant EV abutments* and the implants cleared under the same 510(k) as *Astra Tech EV Implant*.

This Special 510(k) bundled premarket notification includes minor modifications to both the Primary Predicate (A) Astra Tech Implant EV abutments (K120414) and Primary Predicate (B) MultiBase Abutments EV (K163350) devices. All proposed abutments are merged under the same master brand – DS Implants abutments with EV connection. In addition, Primary Predicate (B) MultiBase Abutments EV (K163350) continues to represent the worst-case abutments for fatigue performance testing for all proposed devices.

In addition to the predicate devices listed above, reference device Friadent Aurobase Abutment D3.0 (K030639) is included to demonstrate substantial equivalence in support of biocompatibility.

Reference Device Name	**FDA Product Code**	**510(k)**	**Company Name**
Xive 3.0 Dental Implant system	DZE	K030639	Dentsply Sirona (formerly: Friadent GmbH)

4. Description of Device:

The proposed DS (Dentsply Sirona) Implants abutments with EV connection are used in conjunction with an endosseous dental implant with EV connection to aid in prosthetic rehabilitation in fully edentulous or partially edentulous maxillary and/or mandibular arches.

The proposed devices in this bundled 510(k), which are included under the same master brand – DS Implants abutments with EV connection, include:

(A) Cover Screw EV, Healing Abutment EV, HealDesign EV, Temp Abutment EV, TiDesign EV, CastDesign EV, Abutment Screw EV, and

(B) MultiBase Abutment EV and its accessory components including the Multibase heal cap, MultiBase temporary cylinder, MultiBase semi-burnout cylinder, and MultiBase bridge screw.

These device groupings will be referenced as (A) and (B) throughout this summary.

The proposed devices in this bundled 510(k) are available in the following size ranges.

Table 5.4.1.: Size ranges for proposed DS Implants abutments with EV connection (A) and (B)

Item	Diameter	Gingiva Height	Angulation
Healing Abutment EV	4.0 and 4.3 mm	2.0 - 6.0 mm	0°
HealDesign EV	4.0 - 7.5 mm	2.5 - 6.5 mm	0°
Temp Abutment EV	4.0 - 5.0 mm	12.0 - 12.3 mm	0°
TiDesign EV	4.5 - 7.0 mm	1.5 - 4.5 mm	0° and 15°
CastDesign EV	3.9 and 5.1 mm	7.0 - 7.3 mm	0°
MultiBase Abutment EV	4.5 - 4.9 mm	1.5 - 4.5 mm	0°, 17° and 30°

The proposed (A) CastDesign EV abutment has a metal base and a plastic cylinder, which can be modified by wax-up and cast-to technique. The proposed (A) CastDesign EV abutment is a straight abutment with a minimum post height of 4 mm for single-unit loading applications (i.e. crowns). It is not used to fabricate an angled abutment.

The proposed (B) MultiBase EV accessory MultiBase Semi-Burnout Cylinder has a metal base and plastic cylinder, which can be modified by wax-up and cast-to technique. It is used in the fabrication of a prosthetic restoration in the laboratory. The proposed (B) MultiBase Semi-Burnout Cylinder accessory does not add any additional angular correction than already present in the underlying MultiBase Abutment EV (which allows for angulation of 17° and 30°).

The proposed DS Implants abutments with EV connection (A) and (B), are compatible with
1) Primary Predicate (A) Astra Tech EV Implant (K120414),
2) Astra Tech Implant EV Profile, cleared as OsseoSpeed Profile EV Implant (K130999), and
3) PrimeTaper EV Implant (K210610), which is the new DS Implants brand with EV connection.

The proposed (A) CastDesign EV abutments are not compatible with the Astra Tech Implant EV Profile, cleared as OsseoSpeed Profile EV Implant (K130999).

The purpose of this submission is to expand the assortment of abutments by including additional sizes and variants (diameter and gingiva height), modifications to the shape of the abutments in the lower gingival forming area in some models to facilitate removal of healing abutments or to accommodate to different gingiva heights, slightly deeper grooves on temporary abutments to improve retention towards composite/acrylic of the restoration, and material change in burn-out sleeve (part of the lab fabrication process) for the proposed accessories (A) CastDesign EV and (B) MultiBase Semi-burnout Cylinder models. In addition,

to facilitate product identification, color coding via anodization was added to some abutments which previously did not have such identification. All proposed devices (A) and (B) are merged under the same master brand – DS Implants abutments with EV connection.

5. Indications for Use:
The proposed Indications for Use for DS Implants abutments with EV connection (A) and (B) are:

(A):
DS Implants abutments provided with the EV connection are intended to be used in conjunction with implants with the EV connection in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.

(B):
DS Implants abutments provided with the EV connection are intended to be used in conjunction with implants with the EV connection in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.

The modifications to the Indications for Use for the proposed devices are limited to the brand name change to consolidate the abutments under the new master DS Implants (short for Dentsply Sirona Implants) name and do not alter the intended use of the proposed devices as compared to Primary Predicate (A) Astra Tech Implant EV abutments (K120414) and Primary Predicate (B) Multibase Abutments EV (K163350). The modified Indications for Use state that the abutments are compatible with implants with an EV connection.

6. Substantial Equivalence:

The design of the proposed DS Implants Abutments with EV connection (A) and (B), is based on the previously cleared abutments in the Primary Predicate (A) Astra Tech Implant System Plus (K120414) and Primary Predicate (B) Multibase Abutment EV (K163350) respectively. For some of the proposed abutments, the design remains unchanged and only the indications were updated, whereas some devices underwent minor design changes or additional variations are introduced to the abutment family.

An overview of the similarities and differences between the proposed and predicate abutment devices is given in Table 5.6.1. and Table 5.6.2 below. A discussion of the similarities and differences follows the tables.

Table 5.6.1. Similarities and Differences between the Proposed (A) and Primary Predicate (A) Abutments

	Proposed devices (A) **Dentsply Sirona** **DS Implants Abutments with EV connection**	**Primary Predicate (A)** **Dentsply Sirona** **Astra Tech Implant EV Abutments** **K120414**
Indications for Use	DS Implants abutments provided with the EV connection are intended to be used in conjunction with implants with the EV connection in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.	Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.
Connection sizes	S, M, L	3.0, 3.6, 4.2, 4.8, 5.4
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained
Abutment angulation	TiDesign EV: 0°, 15°	TiDesign Plus: 0°, 15°, 20°
Abutment design	One-piece (0°), Two-piece (0°, 15°)	One-piece (0°), Two-piece (0°, 15°, 20°)
Gingiva Height	Healing Abutment EV: 2, 3, 4, 6 mm HealDesign EV: 2.5, 3.5, 4.5, 6.5 mm TiDesign EV: 1.5, 2.5, 3.5, 4.5 mm	Healing Uni Plus: 2, 3, 4, 6 mm HealDesign Plus: 3.5, 4.5 mm TiDesign Plus: 1.5, 2.5 mm
Materials, **Abutments** **Screw** **Burnout sleeve**	Abutments: Titanium Alloy or Gold Alloy Abutment screws: Titanium Alloy Burn-out sleeve: Plastic	Abutments: Titanium Alloy or Gold Alloy Abutment screws: Titanium Alloy Burn-out sleeve: Plastic
Manufacturing process	Milling	Milling
Surface treatment	Anodization (abutment + abutment screw)	Anodization (abutment + abutment screw)
Sterility state	Sterile or non-sterile	Sterile or non-sterile
Sterilization method for sterile products	E-beam irradiation	E-beam irradiation
Sterilization for non-sterile products	Moist heat (steam) sterilization	Moist heat (steam) sterilization

Table 5.6.2. Similarities and Differences between the Proposed (B) and Primary Predicate (B) Abutments

	Proposed devices (B) **Dentsply Sirona DS Implants Abutments with EV connection**	**Primary Predicate (B)** **Dentsply Sirona Multibase Abutment EV K163350**
Indications for Use	DS Implants abutments provided with the EV connection are intended to be used in conjunction with implants with the EV connection in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.	The Multibase Abutments EV are intended to be used in conjunction with Astra Tech Implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.
Connection sizes	S, M, L	3.6, 4.2, 4.8
Prosthesis Attachment	Screw-retained	Screw-retained
Abutment angulation	MultiBase Abutment EV: 0°, 17°, 30°	Multibase Abutment EV: 0°, 17°, 30°
Abutment design	One-piece (0°), Two-piece (17°, 30°)	One-piece (0°), Two-piece (17°, 30°)
Gingiva Height	MultiBase Abutment EV: 1.5, 2.5, 3.5, 4.5 mm	MultiBase Abutment EV: 1.5, 2.5, 3.5 mm
Materials, **Abutments** **Screw** **Burnout sleeve** **Holder**	Abutments: Titanium Alloy or Gold Alloy Abutment screws: Titanium Alloy Burn-out sleeve: Plastic MultiBase holder: Plastic	Abutments: Titanium Alloy Abutment screws: Titanium Alloy MultiBase holder: Plastic
Manufacturing process	Milling	Milling
Surface treatment	Anodization (abutment + abutment screw)	Anodization (abutment screw)
Sterility state	Sterile or non-sterile	Sterile
Sterilization method for sterile products	E-beam irradiation	E-beam irradiation
Sterilization for non-sterile products	Moist heat (steam) sterilization	Moist heat (steam) sterilization

The proposed DS Implants abutments with EV connection (A) and (B) have the same intended use, similar indications for use, same prosthesis attachment method (screw-retained or cement retained), and same manufacturing, packaging, and sterilization processes as the Primary Predicate (A) Astra Tech Implant EV Abutments (K120414) and Primary Predicate (B) Multibase Abutments EV (K163350) respectively. The proposed and primary predicate abutments and accessories (K120414, K163350) are either one-piece or two-piece abutment designs and made of the same materials with the exception of the burn-out sleeve (part of the lab fabrication process) for the proposed accessories (A) CastDesign EV and (B) MultiBase Semi-burnout Cylinder models, which are made of the same materials as cleared in Dentsply Sirona devices (K030639 and K945847, respectively).

For the proposed DS Implants abutments with EV connection (A) and (B), designators S, M and L are used instead of a reference to implant diameter size. Size S has identical interface dimensions as 3.6 connection, size M has identical interface dimensions as 4.2 connection and size L has identical interface dimensions as 4.8 connection. Color coding and size legend are located in the compatible Implants Instructions for Use. The proposed devices have EV connection sizes within the range of the primary predicate devices (A) and (B) and the available sizes have identical interface dimensions as primary predicate devices (A) and (B).

The proposed (A) HealDesign EV, TiDesign EV, and (B) MultiBase Abutment EV abutments are available in additional gingiva heights, but those changes do not introduce a new worst-case abutment-implant configuration. In addition, the angulation for the proposed devices (A) and (B) is within the range of primary predicate devices (A) K120414 and (B) K163350. Angulation of 30° continues to be the worst-case for both proposed and predicate devices.

7. Non-Clinical Performance Data

FDA document "Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments Class II Special Controls Guidance Document Guidance for Industry and FDA Staff" was used for determining the performance testing required for the proposed DS Implants Abutments with EV connection.

The addition of the proposed abutment variants does not change the previously defined worst-case abutment-implant combination scenario. It was determined that the abutment with the highest angulation (MultiBase Abutment EV, 30°) continues to be the worst-case for fatigue testing, representing the entire assortment of DS Implants abutments with EV connection. Furthermore, the Primary Predicate (B) 30º MultiBase Abutment EV (K163350) and the proposed (B) 30º MultiBase Abutment EV are identical and therefore fatigue testing performed on Primary Predicate (B) remains valid for the worst-case combinations of proposed abutments (A) and (B) and compatible implants. Therefore, no new fatigue performance data is provided in this submission in support of substantial equivalence.

The fatigue test results obtained with the existing worst-case abutment together with the compatible implants with EV connection, PrimeTaper EV (K210610), AstraTech EV Implant (K120414) and OsseoSpeed Profile EV (K130999), indicate that the proposed DS Implants abutments with EV connection (A) and (B) perform as intended.

Biocompatibility evaluation in accordance with EN ISO 10993-1:2018 *(Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process)* was performed. This included a review of existing cytotoxicity testing on file for reference device Friadent Aurobase Abutment D3.0 (K030639). It was determined that no additional testing was required to demonstrate biological safety of proposed devices.

The proposed DS Implants abutments with EV connection (A) and (B) sterile device modifications do not introduce a new worst-case scenario to sterilize and therefore a new electronic beam (E-beam) irradiation sterilization validation was not performed. The existing

validation for primary predicate devices (A) K120414 and (B) K163350, which meets the requirements according to ISO 11137-1:2006 (*Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)])* and ISO 11137-2:2013 (*Sterilization of health care products - Radiation - Part 2:Establishing the sterilization dose)*, remains valid.

No new steam heat sterilization validation was required on the proposed DS Implants abutments with EV connection (A) and (B) non-sterile devices as the modifications do not introduce a new worst-case scenario to sterilize. The existing validation for primary predicate devices (A) K120414 and (B) K163350 according to ISO 17665-1:2006 *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices)* remains valid.

The shelf life of the proposed sterile DS Implants Abutments with EV Connection (A) and (B) is five (5) years. The packaging materials and configuration for the proposed sterile DS Implants Abutments with EV Connection (A) and (B) are the same as that of the primary predicate devices (A) K120414 and (B) K163350. Therefore, the same shelf life is applicable for the proposed sterile devices (A) and (B), including predicate packaging validation which meets the requirements of ISO 11607-1: 2019 *(Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems).*

8. Clinical Performance Data
   No human clinical data was included to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence
   The information included in this bundled premarket notification supports the substantial equivalence of the proposed DS Implants abutments with EV connection (A) and (B) with the Primary Predicate (A) AstraTech Implant EV Abutment (K120414) and Primary Predicate (B) MultiBase Abutment EV (K163350). The proposed devices have the same intended use, similar indications for use and performance characteristics as the legally marketed primary predicate devices. As a result of the minor modification in indications for use and minor modifications in design and materials, no additional performance testing is included in this premarket notification to demonstrate substantial equivalence.