November 16, 2022

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

Re: K221094
Trade/Device Name: OmniTaper EV Dental Implants, DS Implants abutments with EV connection
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 20, 2022
Received: October 20, 2022

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 -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)*

K221094

Device Name

OmniTaper EV Dental Implants

Indications for Use *(Describe)*

The implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

• Replacing missing teeth in single or multiple unit applications in the mandible or maxilla.
• Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
• Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective.
• Immediate and early loading for all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type 4) where implant stability may be difficult to obtain and immediate loading may not be appropriate.
• The intended use for OmniTaper EV Ø3.0 implant is limited to replacement of maxillary lateral incisors and mandibular incisors.

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)*

K221094

Device Name

DS Implants abutments with 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221094

Device Name

DS Implants abutments with 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)

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510(k) SUMMARY
for
K221094 - OmniTaper EV Dental Implants and Abutments

1. Submitter Information:

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

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

Date Prepared: November 10, 2022

2. Device Name:

- Proprietary Name: *OmniTaper EV Dental Implants, DS Implants abutments with EV connection*
- Classification Name: *Implant, Endosseous, Root-form*
  Abutment, Implant, Dental Endosseous
- Classification Number: *872.3640*
- Device Class: *Class II*
- Product Codes: *Primary product code: DZE*
  Secondary product code: NHA

3. Predicate and Reference Devices:

The proposed devices in this bundled 510(k) include bundles **(A)** and **(B)**:

(A) OmniTaper EV Dental Implants, and

(B) DS Implants abutments with EV Connection

There are two predicate devices identified relating to the substantial equivalence for the proposed devices (A) and (B), as referred to above as bundles (A) and (B):

Predicate Device (A) Name	**510(k)**	**Company Name**
OsseoSpeed Plus Implants*	K120414	Dentsply Sirona (Formerly: Astra Tech AB)
Predicate Device (B) Name	**510(k)**	**Company Name**
DS Implants abutments provided with the EV connection	K213449	Dentsply Sirona

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

(A) Astra Tech EV Implants (K120414) and the abutments cleared under the same 510(k) as compatible Astra Tech EV Abutments (K120414)

In addition, four reference devices are identified to support any differences in technological characteristics:

Reference Device Name	510(k)	Company Name
Xive S Plus Dental Implant System	K073075	Dentsply Sirona (formerly: Dentsply International)
PrimeTaper EV Dental Implant System	K210610	Dentsply Sirona
Xive Dental Implant System Friadent TempBase EV Abutment (Ø3.5 - Ø5.5)	K013867	Dentsply Sirona (formerly: Friadent GmbH)
Xive 3.0 Dental Implant System Friadent TempBase EV Abutment (Ø3.0)	K030639	Dentsply Sirona (formerly: Friadent GmbH)

4. Description of Device:

The proposed (A) OmniTaper EV Dental Implants are root form endosseous implants intended for use by a dental clinician in the prosthetic restoration of chewing function in edentulous human jaws. The proposed (A) OmniTaper EV Dental Implants have the identical implant-abutment connection geometry as predicate (A) Astra Tech EV Implants (K120414). The proposed (A) OmniTaper EV Dental Implants are therefore compatible with the Astra Tech EV Abutments (K120414).

The proposed (B) DS Implant abutments with EV connection include the following abutments and accessories:

- TempBase EV, and its accessory component TempBase Cap
- Cover Screw EV
- Healing Abutment EV
- HealDesign EV
- TempAbutment EV
- TiDesign EV
- CastDesign EV
- MultiBase Abutment EV
- Abutment Screw EV

The proposed (B) DS 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. They are prosthetic abutments that are:

- Compatible with the proposed (A) OmniTaper EV implants,
- Represent an additional abutment type (TempBase EV abutment and cap),

- Introduce additional abutment sizes (XS - Extra Small and XL - Extra Large) to the predicate (B) DS Implants abutments with EV Connection in sizes S (Small), M (Medium) and L (Large) (K213449).

The proposed (B) DS Implant abutments with EV connection have the identical implant-abutment connection geometry as predicate (B) DS Implants abutments with EV connection (K213449) and the Astra Tech EV Abutments (K120414), and are therefore also compatible with predicate (A) Astra Tech EV Implants (K120414).

The proposed (A) OmniTaper EV Dental Implants and proposed (B) DS Implants abutments with EV connection are single-use devices.

The proposed (A) OmniTaper EV implant with pre-mounted proposed (B) TempBase EV abutment, and the proposed (B) devices Cover Screw EV, Healing Abutment EV, HealDesign EV and (B) Multibase Abutment EV are provided sterile via Electronic-Beam (E-beam) irradiation.

The proposed (B) TiDesign EV, CastDesign EV, TempAbutment EV, TempBase Cap and Abutment Screw are provided non-sterile. Devices provided non-sterile are to be sterilized via steam sterilization, or as in the case of the TempBase Cap, cleaned/disinfected, by the end user prior to use per the Instructions for Use.

Risk analysis for the proposed devices was conducted in accordance with ISO 14971:2019, *"Medical Devices: Application of Risk management to medical devices"*. Risks listed in the FDA guidance document *"Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments Class II Special Controls Guidance Document Guidance for Industry and FDA Staff"* were addressed and all risks associated with the proposed implants and abutments were acceptable and as low as possible.

5. Indications for Use:

The Indications for Use for the proposed (A) OmniTaper EV Dental Implants are:

The implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- *Replacing missing teeth in single or multiple unit applications in the mandible or maxilla.*
- *Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.*
- *Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective.*
- *Immediate and early loading for all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type 4) where implant stability may be difficult to obtain, and immediate loading may not be appropriate.*
- *The intended use for OmniTaper EV Ø3.0 implant is limited to replacement of maxillary lateral incisors and mandibular incisors.*

All proposed (B) DS Implants abutments with EV connection, with the exception of the MultiBase Abutment EV, fall under the first indications for Use statement below. The second Indications for Use statement applies to the proposed (B) MultiBase Abutment EV.

DS Implants abutments with EV connection:
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.

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.

6. Comparison of Technological Characteristics:

The proposed (A) OmniTaper EV implants are a new line of endosseous dental implants which are identical with regards to material, surface treatment and internal implant-abutment connection geometry (i.e. the EV connection) as the predicate (A) Astra Tech EV Implants (K120414). The implant dimensions and outer implant design with thread design properties, thread pitch, self-tapping apical thread, condensing upper section and micro-extended implant shoulder of the proposed (A) OmniTaper EV implants are the same or very similar to reference device Xive S Plus implants (K073075). The proposed (A) OmniTaper EV implant also shares the same packaging as the reference device (K073075).

The proposed (B) DS Implants abutments with EV connection are based on the design of the predicate (B) DS Implants Abutments (K213449). It is a line extension of the assortment of compatible EV abutments by:

- adding an abutment type (TempBase EV abutment and Cap) and
- adding abutment sizes (XS - Extra Small and XL - Extra Large) to the predicate (B) DS Implants abutments with EV Connection (K213449).

The design of the proposed (B) TempBase EV abutment is similar to reference device Friadent TempBase Abutments (K030639, K013867) in that the proposed (B) TempBase EV abutment has an EV connection, while the reference device Friadent TempBase Abutments (K030639, K013867) are designed for a hexagonal implant connection. The proposed (B) TempBase EV is pre-mounted on the proposed (A) OmniTaper EV Implant and are packaged together in very similar packaging as reference device Xive S Plus implant (K073075). The proposed (B) accessory component TempBase Cap has identical design and material as reference device Friadent TempBase Cap (K013867) and is cleaned and disinfected in the same way.

The proposed (B) DS Implants abutments with EV connection (XS, XL) and predicate (B) DS Implants abutments with EV connection (K213449) have the same intended use, same Indications for Use, same materials, same design (one-piece or two-piece), same prosthesis attachment method (screw-retained or cement-retained), same manufacturing, same packaging (sterile and non-sterile) and same sterilization method as the predicate (B) abutments (K213449).

An overview of the similarities and differences between the proposed devices (A) and (B) and predicate (A) and (B) devices, including reference devices, are given in Table 1 through Table 4 below.

Table 1: Similarities and Differences between the Proposed (A) and Predicate (A) Dental Implants Indications for Use

Item	Proposed device (A) Dentsply Sirona OmniTaper EV Dental Implants	Predicate device (A) Dentsply Sirona Astra Tech EV Implants (K120414)	Comparison Discussion
Indications for Use	The implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • Replacing missing teeth in single or multiple unit applications in the mandible or maxilla. • Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. • Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective. • Immediate and early loading for all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type 4) where implant stability may be difficult to obtain, and immediate loading may not be appropriate. • The intended use for OmniTaper EV Ø3.0 implant is limited to replacement of maxillary lateral incisors and mandibular incisors.	The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • Replacing single and multiple missing teeth in the mandible and maxilla, • Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • Immediate loading in all indications, except in single tooth situations on implant shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. • The intended use for OsseoSpeed Plus 3.0 S is limited to replacement of maxillary lateral incisors and mandibular incisors.	The Indications for Use of the proposed and predicate implants are similar. The indications of the proposed and predicate device have slight differences in wording, for clarification only. For the proposed (A) device, “early loading” was added to describe the loading protocol of the implant in more detail. The differences in the proposed and predicate Indications for Use do not substantively alter the meaning.

Table 2: Similarities and Differences between the Proposed devices (A), Predicate devices (A), and Reference Device Dental Implants Technological Characteristics

Item	Proposed devices (A) Dentsply Sirona OmniTaper EV Dental Implants	Predicate devices (A) Dentsply Sirona AstraTech EV Dental Implants (K120414)	Reference devices Dentsply Sirona Xive S Plus implants (K073075)	Comparison Discussion
Implant material	Commercially pure titanium (Grade 4) (ASTM F67-13 (2017))	Commercially pure titanium (Grade 4) (ASTM F67-13 (2017))	Commercially pure titanium (Grade 2) (ASTM F67-13 (2017))	Same as predicate device (A) (K120414).
Surface treatment	TiO_2 blasted and acid etched	TiO_2 blasted and acid etched	Grit blasted and acid etched	Same as predicate device (A) (K120414).
Connection type	Conical connection with indexes (EV Connection)	Conical connection with indexes (EV Connection)	Internal hexagonal connection	Same as predicate device (A) (K120414).
Implant design	Cylindrical, threaded, self-tapping apical thread	Cylindrical, threaded	Cylindrical, threaded, self-tapping apical thread	Same as reference device (K073075).
Neck design	(Micro)extended implant shoulder	Cylindrical with micro-threads	(Micro)extended implant shoulder	Same as reference device (K073075).
Type of implantation	Bone level implant	Bone level implant	Bone level implant	Same.
Sites in body	Mandible/maxilla Ø 3.0 diameter implant: Limited to maxillary lateral incisors and mandibular incisors	Mandible/maxilla Ø 3.0 diameter implant: Limited to maxillary lateral incisors and mandibular incisors	Mandible/maxilla Ø 3.0 diameter implant: Limited to maxillary lateral incisors and mandibular incisors	Same.
Implant diameter and length	Ø 3.0 x L 11, 13 and 15 mm Ø 3.4 x L 9.5, 11, 13, 15 and 18 mm Ø 3.8 x L 8, 9.5, 11, 13, 15 and 18 mm Ø 4.5 x L 8, 9.5, 11, 13, 15 and 18 mm Ø 5.5 x L 8, 9.5, 11, 13 and 15 mm	Ø 3.0 x L 8, 9, 11, 13 and 15 mm Ø 3.6 x L 6, 8, 9, 11, 13, 15 and 17 mm Ø 4.2 x L 6, 8, 9, 11, 13, 15 and 17 mm Ø 4.8 x L 6, 8, 9, 11, 13, 15 and 17 mm Ø 5.4 x L 6, 8, 9, 11, 13 and 15 mm	Ø 3.0 x L 11, 13 and 15 mm Ø 3.4 x L 9.5, 11, 13, 15 and 18 mm Ø 3.8 x L 8, 9.5, 11, 13, 15 and 18 mm Ø 4.5 x L 8, 9.5, 11, 13, 15 and 18 mm Ø 5.5 x L 8, 9.5, 11, 13 and 15 mm	Same as reference device (K073075) with minor modification to the outer geometry thickness of material for 8 mm length implants (Ø 3.8, 4.5, and 5.5) only, which do not represent new worst case implants. Substantial equivalence is supported by fatigue testing with similar results compared to predicate device (A) (K120414).

Item	Proposed devices (A) Dentsply Sirona OmniTaper EV Dental Implants	Predicate devices (A) Dentsply Sirona AstraTech EV Dental Implants (K120414)	Reference devices Dentsply Sirona Xive S Plus implants (K073075)	Comparison Discussion
Angulation of compatible abutments	XS (Ø3.0): 0°, 15° S – L (Ø3.4-4.5): 0°, 15°, 17°, 20°, 30° XL (Ø5.5): 0°, 15° (Compatible abutments cleared in K120414, K121810, K163350, K111287, K130999, K112138, K213449)	Ø3.0: 0°, 15° Ø3.6-4.8: 0°, 15°, 17°, 20°, 30° Ø5.4: 0° (Compatible abutments cleared in K120414, K121810, K163350, K183079, K111287, K130999, K112138, K213449)	Ø3.0: 0°, 15° Ø3.4-5.5: 0°, 15°, 30° (Compatible abutments cleared in K945847, K980630, K982576, K994174, K994376, K013438, K013867, K030639, K072730, K093780, K122268, K183079)	Proposed (A) device is compatible with abutments within the same range of angulation as the reference implants (K073075). Substantial equivalence is supported by fatigue testing with similar results compared to predicate device (A) (K120414).
Reusability	Single use	Single use	Single use	Same.
Sterility state	Sterile	Sterile	Sterile	Same.
Sterilization method	Electron-beam irradiation	Electron-beam irradiation	Gamma irradiation	Same as predicate device (A) (K120414)

Table 3: Similarities and Differences between the Proposed (B) and Predicate (B) Dental Abutments Indications for Use

Item	Proposed device (B) Dentsply Sirona DS Implants Abutments with EV connection	Predicate device (A) Dentsply Sirona DS Implants Abutments with EV connection (K213449)	Comparison Discussion
Indications for Use	DS Implants abutments with EV connection: 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. MultiBase Abutment 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.	DS Implants abutments with EV connection: 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. MultiBase Abutment 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.	Same.

Table 4: Similarities and Differences between the Proposed (B), Predicate (B), and Reference Dental Abutments

Item	Proposed device (B) Dentsply Sirona DS Implants Abutments with EV connection	Predicate device (A) Dentsply Sirona DS Implants Abutments with EV connection (K213449)	Reference devices Dentsply Sirona Xive Dental Implant System Abutments and Accessories (K013867, K030639)	Comparison Discussion
Connection Size	XS, XL TempBase EV Abutment and Cap: XS, S, M, L, XL	S, M, L	Friadent TempBase Abutment and TempBase Cap: D3.0, D3.4, D3.8, D4.5, D5.5	Expansion of offering to include XS and XL abutments compatible with proposed (A) device. Addition of TempBase EV abutment and Cap in all sizes. Substantial equivalence supported by fatigue testing.
Prosthesis attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	TempBase Abutment: Screw-retained	Same
Abutment angulation	TiDesign EV: 0°, 15° MultiBase EV: 0° TempBase EV: 0° CastDesign EV: 0°	TiDesign EV: 0°, 15° MultiBase EV: 0°, 17°, 30° CastDesign EV: 0°	TempBase Abutment: 0°	TiDesign EV: Same as predicate device TempBase EV: Same as reference device MultiBase EV: Proposed (B) MultiBase abutments (XS) and (XL) are not available as an angulated abutment. CastDesign EV: Straight abutment, no angular correction. Same as predicate device.
Abutment design	One-piece (0°), Two-piece (0°,15°)	One-piece (0°), Two-piece (0°,15°)	TempBase Abutment: One-piece (0°)	Same
Gingiva height	Healing Abutment EV: 2, 3, 4, 6 mm HealDesign EV: 2.5, 3.5, 4.5, 6.5 mm TiDesign EV:	Healing Abutment EV: 2, 3, 4, 6 mm HealDesign EV: 2.5, 3.5, 4.5, 6.5 mm TiDesign EV:	Not applicable for substantial equivalence	Same as predicate device.

Item	Proposed device (B) Dentsply Sirona DS Implants Abutments with EV connection	Predicate device (A) Dentsply Sirona DS Implants Abutments with EV connection (K213449)	Reference devices Dentsply Sirona Xive Dental Implant System Abutments and Accessories (K013867, K030639)	Comparison Discussion
	1.5, 2.5, 3.5, 4.5 mm MultiBase Abutment EV: 1.5, 2.5, 3.5, 4.5 mm	1.5, 2.5, 3.5, 4.5 mm MultiBase Abutment EV: 1.5, 2.5, 3.5, 4.5 mm		
Materials	Abutments: Titanium Alloy or Gold Alloy Abutment screws: Titanium Alloy Abutment holder: PEEK Burn-out sleeve and TempBase Cap: Plastic	Abutments: Titanium Alloy or Gold Alloy Abutment screws: Titanium Alloy Abutment holder: PEEK Burn-out sleeve Plastic	TempBase Abutment: Titanium Alloy TempBase Cap: Plastic	Same
Manufacturing Process	Milling	Milling	Milling	Same
Surface treatment	Anodization (abutment + abutment screw)	Anodization (abutment + abutment screw)	Anodization (abutment)	Same
Reusability	Single use	Single use	Single use	Same
Sterility state	Sterile or non-sterile	Sterile or non-sterile	Sterile or non-sterile	Same
Sterilization method for sterile products	E-beam irradiation	E-beam irradiation	Gamma irradiation	Same as predicate device
Sterilization for non-sterile products	Moist heat (steam) sterilization	Moist heat (steam) sterilization	Moist heat (steam) sterilization	Same
Cleaning of TempBase Cap	Clean/disinfect with Cidex OPA prior to use	Not applicable	Clean/disinfect with Cidex OPA prior to use	Same as reference device

7. Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence includes the following:

Sterilization Validation and Shelf Life:

The proposed sterile (A) OmniTaper EV Dental Implants, with pre-mounted proposed (B) TempBase EV, and proposed sterile (B) DS Implants abutments with EV Connection, which include the proposed (B) Cover Screw EV, Healing Abutment EV, HealDesign EV and MultiBase Abutment EV, are provided sterile via Electronic-Beam (E-beam) irradiation. The sterilization process for the proposed sterile devices (A) and (B) was validated to a sterility assurance level (SAL) of 10^{-6} in accordance with:

- 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"* and
- ISO 11137-2:2013, *"Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose"*.

No new steam heat sterilization validation was required on the proposed non-sterile (B) DS Implants abutments with EV connection as the modifications do not introduce a new worst-case scenario to sterilize. The proposed (B) abutments are adopted into the existing sterilization validation performed 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"*.

The proposed non-sterile (B) TempBase Cap is not heat resistant and must not be steam sterilized. The proposed (B) TempBase Cap must be cleaned and disinfected in a cold disinfectant solution. Since the reference device Friadent TempBase Cap (K013867) is identical to the proposed cap, the cleaning and chemical disinfection validation of the reference device (K013867) remains valid for the proposed (B) TempBase Cap. The existing cleaning validation was performed according to:

- ASTM E 1837:2014, *"Standard Test Method to determine efficacy of disinfection processes for reusable medical devices (simulated use test)"*
- ASTM E 2314:2014, *"Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (simulated use test)"*.

The proposed devices (A) and (B) will not be marketed as non-pyrogenic. During routine production, the method used to determine that the proposed sterile devices (A) and (B) meet the established pyrogen limit is the Limulus amebocyte lysate (LAL) test according to the United States Pharmacopeial Convention, Inc. USP <85> "*Bacteria Endotoxins Test"*.

Both the proposed (A) OmniTaper EV Implants (with pre-mounted proposed (B) TempBase EV abutment) and reference Xive S Plus (K073075) devices have a shelf life of five years and share very similar packaging. To ensure packaging integrity after simulated distribution and accelerated aging, the packaging of the reference device (K073075) was tested for dye penetration and seal strength according to the following standards and validation remains the same for the proposed (A) implants:

- ASTM F 1929-15, "*Standard test method for detecting seal leaks in porous medical packaging by dye penetration",*
- ISO 11607-1:2019, "*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems",* and
- EN 868-10:2018, "*Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods".*

The packaging materials, configuration, and shelf life (5 years) for the proposed (B) sterile and non-sterile devices are the same as predicate (B) devices (K213449). The existing packaging validation remains valid according to:

- ISO 11607-1: 2019, "*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems".*

The proposed (B) non-sterile TempBase Cap is identical in product material, manufacturing process, and packaging when compared to the reference device Friadent TempBase Cap (K013867) and therefore no new testing is provided in this pre-market submission. The proposed non-sterile TempBase Cap is composed of the inherently stable plastic material Polypropylene which is not adversely affected by aging and known to be stable at room temperature.

Biocompatibility Testing:

Biocompatibility evaluation assessment for the proposed devices (A) and (B) was performed in accordance with ISO 10993-1:2018 *"Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process"* and FDA guidance document, "*Use of International Standard ISO 10993-1, '"Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process'".*

Results of biocompatibility testing, which include cytotoxicity according to ISO 10993-5:2009 "*Biological evaluation of medical devices – Part 5: tests for in vitro cytotoxicity"*, gas chromatography (GC-MS) and Fourier transformation infrared spectroscopy (FT-IR) according to ISO 10993-18:2020 "*Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process"*, and results of pyrogenicity testing via monocyte activation testing, confirm that the proposed (A) and (B) devices are biocompatible.

Fatigue Testing:

Dynamic fatigue testing was conducted according to ISO 14801:2016 *"Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants"*. The worst-case implant-abutment combination of the proposed (A) and (B) devices was selected based on the FDA Guidance, "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments"* and test results were compared with predicate (A) and (B) devices. Test results demonstrate that the proposed devices (A) and (B) perform as intended and do not raise new questions regarding safety and performance. Fatigue testing was also performed on other compatible abutments to confirm compatibility.

MRI Testing:

The following testing or analysis was performed on the worst-case implant combination for Dentsply Sirona implant products:

- Magnetically induced displacement force, according to ASTM F2052-21, *Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment*
- Magnetically induced torque, according to ASTM F2213-17, *Standard test method for measurement of magnetically induced torque on medical devices in magnetic resonance environment*
- Image Artifact, according to ASTM F2119-07 (2013), *Standard test method for evaluation of MR image artifacts from passive implants*
- RF Induced Heating Simulation using Computational modeling and simulation (CM&S)

Based on the test or analysis results, proposed device labeling for the proposed (A) OmniTaper EV Dental Implants implant and (B) DS Implants abutments will indicate MRI Conditional. The TempBase Cap (B) will be labeled as MR Safe.

The performance of the proposed devices (A) OmniTaper EV Dental Implants and (B) DS Implants abutments with EV Connection satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

8. Clinical Performance Data

No human clinical studies were performed on the device to support substantial equivalence.

However, published literature on reference Xive S Plus D 3.0 implant (K073075), which has the same narrow implant outer design, can be used to support clinical relevance and safe long-term use of the proposed (A) OmniTaper EV implant Ø3.0. Four (4) peer-reviewed scientific publications presented 1 to 4 years of prospective clinical follow-up data on reference Xive S Plus D 3.0 implants (K073075). More than 580 implants have been placed in upper lateral- and lower incisal positions, as well as in the posterior regions. Based on high survival rates (mean >99%) and stable marginal bone around the implants, the studies confirm that the narrow 3.0 mm implant is a reliable treatment option for replacing missing teeth.

9. Conclusion

The information included in this bundled premarket notification supports the substantial equivalence of the proposed (A) OmniTaper EV Dental Implants and proposed (B) DS Implants abutments with EV Connection with the predicate (A) Astra Tech EV Implants (K120414) and predicate (B) DS Implants Abutments with EV connection (K213449), respectively. The proposed devices (A) and (B) have the same intended use, incorporate the same fundamental technology, and have similar or same indications for use as the predicate devices (A) and (B). The non-clinical testing data and clinical data (literature review) do not raise new questions regarding the safety and performance of the proposed (A) OmniTaper EV Dental Implants and proposed (B) DS Implants abutments with EV Connection as compared to predicates (A) and (B) and reference devices (K073075, K210610, K013867, K030639), which support a conclusion of substantial equivalence.