November 16, 2022

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

Re: K220841
Trade/Device Name: PrimeTaper EV Dental Implants Ø3.0, DS Implants abutments with EV connection (XS)
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)*

K220841

Device Name
PrimeTaper EV Dental Implant Ø3.0

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 implant 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 PrimeTaper EV Ø3.0 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*

K220841

Device Name
DS Implants abutments with EV Connection XS

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
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)*

K220841

Device Name
DS Implants abutments with EV Connection XS

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
K220841- PrimeTaper EV Dental Implants Ø3.0 and Abutments (XS)

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: *PrimeTaper EV Dental Implants Ø3.0*
  DS Implants abutments with EV connection (XS)
- 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) PrimeTaper EV Dental Implants Ø3.0, and

(B) DS Implants abutments with EV Connection XS.

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*	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) device *Astra Tech EV Implants (K120414)* and the abutments cleared under the same 510(k) as reference device *Astra Tech EV Abutments (K120414)* to the proposed (A) abutments. The implant system (implants and abutments) will be referred to as *Astra Tech Implant System EV* (K120414).

In addition, there are five reference devices identified and listed below.

Reference Device Name	510(k)	Company Name	Reason for inclusion
PrimeTaper EV Implant	K210610	Dentsply Sirona	Same implant design, labeling, biocompatibility, packaging and sterilization as proposed (A) implants
OsseoSpeed Plus - Astra Tech EV Abutments Ø3.0	K120414	Dentsply Sirona (formerly: Astra Tech AB)	Same EV conical connection, materials, and diameter as proposed (B) abutments
OsseoSpeed Narrow	K080396	Dentsply Sirona (formerly: Astra Tech AB)	Published clinical data on this smaller sized implant is included to support performance and safety of implants smaller than 3.25 mm, such as the proposed (A) implants
Esthetic Abutment Conical Connection 3.0	K111581	Nobel Biocare AB	Has the same narrow diameter (3.0 mm) and range of gingiva heights (1.5 – 4.5 mm) as proposed (B) TiDesign EV (XS) abutments
Atlantis Healing Abutment	K193529	Dentsply Sirona	Compatible with proposed (A) dental Implant Ø3.0.

4. Description of Device:

The proposed (A) PrimeTaper EV Dental Implant Ø3.0 is a root form endosseous implant which is intended for use by a dental clinician in the prosthetic restoration of chewing function in edentulous human jaws. It represents an additional extra small implant diameter (3.0 mm diameter implant) to reference device PrimeTaper EV Dental Implants (K210610).

The proposed (A) PrimeTaper EV Dental Implant Ø3.0 has the identical implant-abutment connection geometry as the predicate (A) Astra Tech EV Implant (K120414), and is therefore compatible with the reference device Astra Tech EV Abutments (K120414) with 3.0 mm diameter of the Astra Tech Implant System EV (K120414).

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

- TiDesign EV (XS)
- MultiBase Abutment EV (XS)
- TempAbutment EV (XS)
- Healing Abutment EV (XS)
- HealDesign EV (XS)
- Cover Screw EV (XS)
- Abutment Screw EV (XS)

The proposed (B) DS Implants abutments with EV connection XS 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 compatible with the proposed (A) PrimeTaper EV Dental Implant Ø3.0 and represent an additional

extra small abutment-implant diameter (XS, 3 mm diameter) to the Predicate (B) DS Implants abutments with EV Connection in sizes S (small), M (medium) and L (large) (K213449).

The proposed (B) abutments have the identical implant-abutment connection geometry as the reference device Astra Tech EV Abutments (K120414) and are therefore compatible with the predicate (A) Astra Tech EV Implants (K120414) with 3.0 mm diameter.

The proposed (A) PrimeTaper EV Dental Implant Ø3.0 and proposed (B) DS Implants abutments with EV connection XS are single-use devices and are provided sterile by electron-beam irradiation except for TiDesign EV (XS), TempAbutment EV (XS) and Abutment Screw (XS), which are provided non-sterile. Devices provided as non-sterile are sterilized by the end user via steam sterilization.

Risk Analysis - 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 proposed Indications for Use for the proposed **(A)** PrimeTaper EV Dental Implant Ø3.0 is:

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 implant 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 PrimeTaper EV Ø3.0 is limited to replacement of maxillary lateral incisors and mandibular incisors.*

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

DS Implants abutments with EV connection XS:
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 (XS):
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) PrimeTaper EV Dental Implants size Ø3.0 and proposed (B) DS Implants abutments with EV connection XS are a line extension to and are based on the design of the reference device PrimeTaper EV Dental Implant cleared in K210610 and the Predicate (B) DS Implants Abutments cleared in K213449, respectively, to add a new small diameter size (Ø 3 mm).

For the proposed (B) abutments, a new worst-case abutment is introduced. Although the proposed (B) TiDesign EV abutment (XS) comes in the same angulation (maximum of 15º) and specifications as the predicate (B) abutments, the smaller XS diameter makes it a new worst-case abutment. In addition, the TempAbutment has a smaller abutment height compared with the predicate (B) abutments. All other design features remain unchanged and the remaining proposed (B) abutments are within the range of the predicate (B) abutments.

An overview of the similarities and differences between the proposed devices (A) and (B) and predicate devices (A) and (B) is given in Table 1 through Table 3 below. A discussion of the similarities and differences follows the tables.

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

Device	Indications for Use*	Comparison Discussion
Proposed device (A) PrimeTaper EV Dental Implants size Ø3.0 (K220841)	**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 implant 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 **PrimeTaper EV Ø3.0** is limited to replacement of maxillary lateral incisors and mandibular incisors.	The Indications for Use of the proposed and predicate implants are very similar. The addition of "early loading" does not change the intended use nor represent an expansion of the indications for use since "early loading" includes any loading occurring after the immediate placement of the implant. Besides branding and slight rewording, there are no other changes to the indications for use statement.
Predicate device (A) AstraTech EV Implant size Ø3.0 (K120414)	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 implants 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 3.0S** is limited to replacement of maxillary lateral incisors and mandibular incisors.	

*Note: Differences are in **bold and underline**

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

Item	Proposed devices (A) Dentsply Sirona PrimeTaper EV Dental Implants size Ø3.0 (K220841)	Predicate devices (A) Dentsply Sirona AstraTech EV Implants size Ø3.0 (K120414)	Reference devices Dentsply Sirona PrimeTaper EV Dental Implants (K210610)	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 4) (ASTM F67-13 (2017))	Same
Surface treatment	TiO_2 blasted and acid etched	TiO_2 blasted and acid etched	TiO_2 blasted and acid etched	Same
Connection type	Conical connection with indexes (EV Connection)	Conical connection with indexes (EV Connection)	Conical connection with indexes (EV Connection)	Same
Implant design	Tapered design, threaded	Cylindrical, threaded	Tapered design, threaded	Same as reference device.
Neck design	Cylindrical with micro-threads	Cylindrical with micro-threads	Cylindrical with micro-threads	Same
Type of implantation	Bone level implant	Bone level implant	Bone level implant	Same
Sites in body	Limited to maxillary lateral incisors and mandibular incisors	Limited to maxillary lateral incisors and mandibular incisors	Mandible/maxilla	Same as predicate device.
Implant diameter and length	Ø 3.0 x L 8, 9, 11, 13 and 15 mm	Ø 3.0 x L 8, 9, 11, 13 and 15 mm	Ø3.6 x L 8, 9, 11, 13, 15 and 17 mm Ø4.2 x L 6.5, 8, 9, 11, 13, 15 and 17 mm Ø4.8 x L 6.5, 8, 9, 11, 13, 15 and 17 mm Ø5.4 x L 6.5, 8, 9, 11, 13 and 15 mm	Same as predicate device.
Angulation of compatible abutments	Ø3.0: 0°, 15° (compatible abutments cleared in K120414, K130999, K193529)	Ø3.0: 0°, 15° (compatible abutments cleared in K120414, K130999, K193529)	Ø3.6-4.8: 0°, 15°, 17°, 20°, 30° Ø5.4: 0° (compatible abutments cleared in K120414, K121810, K163350, K111287, K193529)	Same as predicate device.
Reusability	Single use	Single use	Single use	Same
Sterility state	Sterile	Sterile	Sterile	Same
Sterilization method	Electron-beam irradiation	Electron-beam irradiation	Electron-beam irradiation	Same

The proposed (A) PrimeTaper EV Dental Implants size Ø3.0 and the predicate (A) Astra Tech EV Implants Ø3.0 (K120414) have the same intended use, very similar indications for use and similar manufacturing, packaging, and sterilization processes. The minor modification in indications for use does not alter the intended use of the proposed (A) devices as compared to predicate (A) devices (K120414). The proposed (A) PrimeTaper EV Dental Implants size Ø3.0 and the Predicate (A) Astra Tech EV Implants Ø3.0 (K120414) encompass the same range of technological characteristics, including implant length, surface treatment and the abutment connection interface. The proposed (A) PrimeTaper EV Dental Implants size Ø3.0 share the same overall implant design, including outer thread design, as the reference device PrimeTaper EV Dental Implant (K210610).

Table 3 compares the Atlantis healing abutment that is compatible with the proposed (A) implant to the Atlantis healing abutment that was cleared in K193529, compatible with the MIS NP/SP/WP implants. K193529 was specific to compatibility with the MIS Conical Connection implants but besides the implant interface connection portion of the healing abutment and additional screw access for the MIS implants, there are no differences between the Atlantis Healing Abutment cleared in K193529 and the Atlantis Healing Abutment that is compatible with the proposed (A) implant.

Table 3: Similarities and Differences between the Atlantis Healing Abutment compatible with the Proposed (A) implant and Reference Device (K193529)

Item	Compatible Atlantis Healing Abutment Dentsply Sirona EV connection Ø3.0 interface	Reference device Dentsply Sirona Atlantis Healing Abutment (K193529)	Comparison
Material	Titanium alloy, Gold-Shaded Titanium (Gold Hue)	Titanium alloy, Gold-Shaded Titanium (Gold Hue)	Same
Surface treatment	N/A	N/A	Same
Connection type	Conical connection with indexes (EV Connection)	Conical connection	Different; The compatible Atlantis healing abutment is connected to an implant with an EV connection.
Neck design	Small abutment core	Small abutment core	Same
Sites in body	Limited to maxillary lateral incisors and mandibular incisors	Upper and lower jaw arches Narrow implants only: Limited to mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws	Different; The compatible Atlantis healing abutment is intended to be connected to a Ø3.0 implant and therefore follows the same limitations of use as the proposed (A) implant.
Compatible devices	Compatible with proposed (A) implant	Platform NP/SP/WP of MIS conical Connection Implants (K172505, K163349)	Different; The compatible Atlantis healing abutment has an interface that is compatible only with the proposed (A) implant.
Screw access to implant	Straight	Straight and angled	Different; The compatible Atlantis healing abutment can only be connected to the proposed (A) implant via a straight access screw.
Reusability	Single Use	Single Use	Same

Item	Compatible Atlantis Healing Abutment Dentsply Sirona EV connection Ø3.0 interface	Reference device Dentsply Sirona Atlantis Healing Abutment (K193529)	Comparison
Packaging	Option 1: Abutment and screw in blister pack (plastic); Sealed blister pack placed in Casesafe box with foam Option 2: Flex-top box (plastic box) with foam	Option 1: Abutment and screw in blister pack (plastic);Sealed blister pack placed in Casesafe box with foam Option 2: Flex-top box (plastic box) with foam	Same
Sterility state	Non-sterile – Steam Sterilized by end user	Non-sterile – Steam Sterilized by end user	Same
Sterilization method	Non-sterile – Steam Sterilized by end user	Non-sterile – Steam Sterilized by end user	Same

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

Item	Proposed device (B) Dentsply Sirona DS Implants Abutments with EV connection (XS) (K220841)	Predicate device (A) Dentsply Sirona DS Implants Abutments with EV connection (K213449)	Reference devices Dentsply Sirona AstraTech EV Abutments size Ø3.0 (K120414)	Reference devices Nobel Biocare AB Esthetic Abutment Conical Connection 3.0 (K111581)	Comparison Discussion
Indications for Use	DS Implants abutments with EV connection XS: 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 (XS): 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.	Not applicable for substantial equivalence discussion.	Not applicable for substantial equivalence discussion.	Same as predicate device.
Connection Type	Internal conical implant-abutment connection with indexes (EV connection)	Internal conical implant-abutment connection with indexes (EV connection)	Internal conical implant-abutment connection with indexes (EV connection)	Internal Conical Connection	Same as predicate device and reference device (K120414).
Connection Sizes	XS	S, M, L	3.0	3.0	Expansion of offering to include XS abutments

Item	Proposed device (B) Dentsply Sirona DS Implants Abutments with EV connection (XS) (K220841)	Predicate device (A) Dentsply Sirona DS Implants Abutments with EV connection (K213449)	Reference devices Dentsply Sirona AstraTech EV Abutments size Ø3.0 (K120414)	Reference devices Nobel Biocare AB Esthetic Abutment Conical Connection 3.0 (K111581)	Comparison Discussion
					compatible with Proposed (A) device. Substantial equivalence supported by fatigue testing.
Prosthesis attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained	Same as predicate device and reference devices. Note: TiDesign EV is a cement retained abutment and therefore has the same prosthesis attachment type as reference device (K111581).
Abutment angulation	TiDesign EV (XS): 0°, 15°	TiDesign EV: 0°, 15°	TiDesign EV (3.0): 0°, 15°	Esthetic abutment 0°, 15°	Same
Abutment design	One-piece (0°), Two-piece (0°,15°)	One-piece (0°), Two-piece (0°,15°)	One-piece (0°), Two-piece (0°, 15°)	Two-piece (0°, 15°)	Same as predicate device and reference devices. Note: TiDesign EV is a two-piece abutment.
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 MultiBase Abutment EV: 1.5, 2.5, 3.5 mm	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 MultiBase Abutment EV: 1.5, 2.5, 3.5, 4.5 mm	Healing Abutment EV: 2, 3, 4, 6 mm HealDesign EV: 3.5, 4.5 mm TiDesign EV: 1.5, 2.5 mm	Esthetic abutment 1.5, 3.0, 4.5 mm	Same as predicate device for Healing Abutment EV, HealDesign EV, and MultiBase Abutment EV. Note: Proposed MultiBase abutment is not available in 4.5 mm gingival height. TiDesign EV is within size range of reference device esthetic abutment (K111581).

Item	Proposed device (B) Dentsply Sirona DS Implants Abutments with EV connection (XS) (K220841)	Predicate device (A) Dentsply Sirona DS Implants Abutments with EV connection (K213449)	Reference devices Dentsply Sirona AstraTech EV Abutments size Ø3.0 (K120414)	Reference devices Nobel Biocare AB Esthetic Abutment Conical Connection 3.0 (K111581)	Comparison Discussion
Materials	Abutments: Titanium Alloy Abutment screws: Titanium Alloy Abutment holder: PEEK	Abutments: Titanium Alloy Abutment screws: Titanium Alloy Abutment holder: PEEK	Abutments: Titanium Alloy Abutment screws: Titanium Alloy	Abutments: Titanium Alloy Abutment screws: Titanium Alloy	Same as predicate device and reference devices.
Manufacturing Process	Milling	Milling	Milling	Milling	Same
Surface treatment	Anodization (abutment + abutment screw)	Anodization (abutment + abutment screw)	Anodization (abutment + abutment screw)	Unknown	Same as predicate device and reference device (K120414)
Reusability	Single use	Single use	Single use	Single use	Same
Sterility state	Sterile or non-sterile	Sterile or non-sterile	Sterile or non-sterile	Non-sterile	Same as predicate device and reference devices.
Sterilization method for sterile products	E-beam irradiation	E-beam irradiation	E-beam irradiation	Not applicable	Same as predicate device
Sterilization for non-sterile products	Moist heat (steam) sterilization	Moist heat (steam) sterilization	Moist heat (steam) sterilization	Moist heat (steam) sterilization	Same

The proposed (B) DS Implants abutments with EV connection (XS) have the same intended use and indications for use, same prosthesis attachment method (screw-retained or cement-retained), and same manufacturing, packaging, and sterilization processes as the predicate (B) DS Implants abutments with EV connection (K213449). The proposed (B) and predicate (B) abutments and accessories (K213449) are either one-piece or two-piece abutment designs, have the same abutment-implant connection interface (EV Connection) and are made of the same materials. Differences include the additional abutment diameter (XS) and changes in abutment height, where applicable. The reference devices (K120414 and K111581) have the same implant platform diameter as the proposed XS abutments and share similar technological characteristics, including gingival height, design, angulation and attachment method.

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) PrimeTaper EV Dental Implants Ø3.0 and (B) DS Implants abutments with EV Connection XS, which include the proposed Cover Screw EV (XS), Healing Abutment EV (XS), HealDesign EV (XS) and MultiBase Abutment EV (XS), 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.*

There are no changes to the sterilization method or processes of the proposed (A) and (B) devices when compared to the reference device (K210610) and predicate (B) device (K213449), respectively.

No new steam heat sterilization validation was required on the proposed (B) DS Implants abutments with EV connection non-sterile devices as the modifications do not introduce a new worst-case scenario to sterilize. The existing validation for predicate device (B) (K213449) 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 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.

For proposed devices (A) and (B), packaging and materials are the same as used for the reference device (K210610) and predicate (B) device (K213449), respectively, and the shelf life is five (5) years. Therefore, the same shelf life is applicable for the proposed sterile devices (A) and (B), including existing 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).*

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"*. The proposed devices (A) and (B) have the same nature of body contact, contact duration, material, packaging, and sterilization method compared to the reference device (K210610) and predicate (B) device (K213449), respectively.

Results of biocompatibility testing which includes 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 spectrometry (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) and reference devices was chosen based on the FDA Guidance, *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*. Test results demonstrate that the proposed devices (A) and (B) perform as intended and support substantial equivalence to the predicate devices.

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 will indicate MRI Conditional.

The performance of the proposed devices (A) PrimeTaper EV Dental Implant Ø3.0 and (B) DS Implants abutments with EV Connection XS 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 dental implants with a diameter less than 3.25 mm was evaluated to support clinical relevance and safe long-term use of the proposed (A) PrimeTaper EV Dental Implant Ø3.0. Six peer-reviewed scientific publications present 1 to 5 years of clinical follow-up data from four (4) different clinical trials. Two hundred narrow diameter implants (reference device, OsseoSpeed 3.0 mm, Astra Tech Implant System (K080396)), that are similar to the proposed (A)

PrimeTaper EV Dental Implant Ø3.0, were placed in the upper lateral and lower incisor spaces, in over 160 patients, and followed up prospectively.

Based on high survival rates (mean >98%) and well-maintained marginal bone around the implants, the authors conclude that the narrow 3.0 mm implant is a reliable treatment option for patients where the alveolar space is limited.

9. Conclusion

The information included in this bundled premarket notification supports the substantial equivalence of the proposed (A) PrimeTaper EV Dental Implant Ø3.0 and proposed (B) DS Implants abutments with EV Connection XS with the predicate (A) device Astra Tech EV Implants Ø 3.0 (K120414) and (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 provided to support a decision of substantial equivalence of the proposed (A) PrimeTaper EV Dental Implant Ø3.0 and proposed (B) DS Implants abutments with EV Connection XS with predicates (A) and (B) do not raise additional questions of safety and effectiveness.