August 27, 2021

Dentsply Sirona, Inc.
Rebecca Sporer
Regulatory Affairs Specialist
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K210610
Trade/Device Name: PrimeTaper EV Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 27, 2021
Received: July 28, 2021

Dear Rebecca Sporer:

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210610

Device Name
PrimeTaper EV Dental Implant

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 IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

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.

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

510(k) SUMMARY
PrimeTaper EV Dental Implant
K210610

5.1 Submitter Information:

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

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Email: Rebecca.sporer@dentsplysirona.com

Date Prepared: 27-August-2021

5.2 Device Name:

- Proprietary Name: PrimeTaper EV Dental Implant
- Classification Name: Endosseous dental implant
- CFR Number: 21 CFR 872.3640
- Device Class: Class II
- Product Code: DZE (Implant, Endosseous, Root-Form)

5.3 Predicate Device:

The primary predicate and reference devices identified relating to the substantial equivalence of the PrimeTaper EV Dental Implant are:

Primary Predicate Device	**510(k)**	**Company Name**
Osseospeed™ Plus	K120414	Dentsply Sirona (former: Astra Tech AB)

Reference Devices	**510(k)**	**Company Name**
MIS Conical Connection Implants	K112162	MIS Implants Technologies Ltd. (Dentsply Sirona)
OsseoSpeed™ Angled Abutment EV	K121810	Dentsply Sirona (former: Astra Tech AB)

Reference Devices	510(k)	Company Name
Multibase Abutments EV and ATLANTIS Suprastructures	K163350	Dentsply Sirona
Conometric Abutments	K183079	Dentsply Sirona
Astra Tech AB Implant System Plus	K111287	Dentsply Sirona (former: Astra Tech AB)

5.4 Device Description:

The proposed PrimeTaper EV Dental Implants are endosseous dental implants, which are manufactured from commercially pure titanium (Grade 4). The implant surface is blasted, and acid etched. The dental implants are intended to be surgically placed in the bone of the mandible and maxilla to replace missing teeth in order to restore chewing function. The proposed PrimeTaper EV Dental Implants have a root form shape with a self-tapping thread design. The coronal portion of the implant has a minute threading (MicroThread™). The residual implant body has macro threads. The proposed implants are available in the diameters 3.6, 4.2, 4.8, 5.4 mm and in the lengths 6.5, 8, 9, 11, 13, 15, 17 mm. The proposed PrimeTaper EV Dental Implants incorporate a conical implant – abutment connection interface with indexing option (EV Connection), which is identical to the internal connection of the predicate OsseoSpeed Plus (K120414) implants. The PrimeTaper EV Dental Implants are intended to be used in combination with prosthetic components with the conical EV connection (cover screws, healing abutments, cement-retained abutments and screw-retained abutments), which were previously cleared for use with the OsseoSpeed Plus Dental Implant System (K120414, K121810, K163350, K183079 and K111287). Dental implant abutments are intended to be used in the upper or lower jaw used for supporting tooth replacements to restore chewing function. No new Abutments are being proposed as part of this submission. The PrimeTaper EV Dental Implants are provided sterile by electron-beam irradiation.

5.5 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 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.

5.6 Substantial Equivalence Discussion

For the purposes of substantial equivalence, the proposed PrimeTaper EV Dental Implants are compared to the predicate device OsseoSpeed™ Plus implants (K120414) as well as to the reference device MIS C1 Conical Connection Implant System cleared under K112162 (Standard and Wide platforms). The proposed PrimeTaper EV Implant device and the predicate device (K120414) have the same intended use, similar indications for use and the same fundamental principles of operation. The proposed devices and the predicate devices encompass the same range of physical dimensions, including diameter, length, surface treatment and the abutment connection interface. The proposed PrimeTaper EV Implant does not include implants with diameter D3.0. Any differences in the technological characteristics between the proposed device and the predicate device have been evaluated via performance testing included in this premarket notification in support of substantial equivalence.

The indications of the proposed PrimeTaper EV Implant are the same as for the cleared predicate device with the following minor changes:

- The indication "immediate loading for all indications, except…" was changed to "immediate and early loading for all indications, except…" to include "early loading" for clarification purposes.
- Reference to implants with diameter D3.0 were removed from the indications for use, since these small diameter implants are not available for the proposed PrimeTaper EV implants.

The proposed PrimeTaper EV Implant system incorporates the identical "EV" implant-to-abutment conical connection interface as does the predicate device OsseoSpeed Plus Implant system (K120414). Abutments previously cleared for use with the OsseoSpeed Plus Implant system under K120414, K121810, K163350, K183079 and K111287, are also compatible prosthetic devices for the subject PrimeTaper EV Implant system. Compatible abutments in the referenced 510(k)s to be used with the proposed PrimeTaper EV implants are listed below:

Reference 510k	**Abutments compatible with PrimeTaper EV**
K120414	Cover Screw EV, HealDesign EV, Healing Uni EV, TiDesign EV, Direct Abutment EV, CastDesign EV, Temp AbutmentEV, Uni Abutment EV
K121810	Angled Abutment EV
K163350	MultiBase Abutment EV
K183079	Conometric Abutment EV
K111287	Atlantis titanium abutment for Osseospeed EV

The proposed PrimeTaper EV Implant is composed of the identical titanium material and incorporates the same surface treatment and is proposed in length and diameter ranges which are within those cleared for the predicate device (K120414).The implant profile of the proposed PrimeTaper EV Implant device is tapered while the predicate OsseoSpeed Plus implant (K120414) features a cylindrical profile. The MIS Conical connection implants reference devices (K112162) are included to support substantial equivalence with respect to the tapered implant profile as the proposed PrimeTaper EV Implant device incorporates the same tapered profile as the reference devices.

A summary of the similarities and differences between the proposed and predicate device is given in Table 1 below.

Table 1: Similarities and Differences between the proposed and predicate Implant devices			
	Proposed Device PrimeTaper EV Dental Implant	**Predicate Device** OsseoSpeed Plus K120414	**Reference Devices** MIS Conical Connection Implants K112162
Manufacturer	**Dentsply Sirona**	**Dentsply Sirona**	**MIS Implants Technologies LTD (Dentsply Sirona)**
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 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 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.	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.
Connection type	Conical with indexes (EV Connection)	Conical with indexes (EV Connection)	Conical with indexes
Intended use of implants	Partial and total edentulism	Partial and total edentulism	Partial and total edentulism

Implant Design	Tapered design, threaded	Cylindrical design, threaded	Tapered design, threaded
Implant diameter and length	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, 15 mm	Ø3.0 x L 8, 9, 11, 13 and 15 mm Ø3.6 x L 6, 8, 9, 11, 13, 15 and 17 mm Ø4.2 x L 6, 8, 9, 11, 13, 15 and 17 mm Ø4.8 x L 6, 8, 9, 11, 13, 15 and 17 mm Ø5.4 x L 6, 8, 9, 11, 13, 15 mm	Ø3.75 x L 8, 10, 11.5, 13 and 16 mm Ø4.2 x L 8, 10, 11.5, 13 and 16 mm Ø5.0 x L 8, 10, 11.5, 13 and 16 mm
Compatible abutments / Prosthetic restoration	Astra Tech Implant System EV prosthetic components with EV conical connection geometry (K120414, K121810, K163350, K183079, K111287,)	Astra Tech Implant System EV prosthetic components with EV conical connection geometry (K120414, K121810, K163350, K183079, K111287)	conical connection abutments
Material(s)	CP Titanium Grade 4	CP Titanium Grade 4	Titanium Alloy
Surface Treatment	TiO_2 blasted and acid etched	TiO_2 blasted and acid etched	Sand blasted and acid etched
Sites in body	Mandible/maxilla	Mandible/maxilla	Mandible/maxilla
Reusability	Single use	Single use	Single use
Sterilization Method	Electronic-beam Irradiation	Electronic-beam Irradiation	Gamma Irradiation

5.7 Non-Clinical Performance Data

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

Sterilization Validation and Shelf Life:

The proposed PrimeTaper EV Dental Implants are provided sterile, sterilized by electron beam irradiation. Sterilization validation is referenced by equivalence to the sterilization validation of the predicate device (K120414) via existing worst-case challenge validations conducted according to *ISO 11137-1 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 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.* The referenced validations conclude that a sterility assurance level (SAL) of 10^{-6} is achieved under the sterilization process parameters utilized. There are no changes to the sterilization method or processes of the proposed PrimeTaper EV Implant device when compared to the predicate device.

Packaging configuration and packaging materials utilized for the proposed PrimeTaper EV Implant device are identical to the predicate OsseoSpeed Plus device as cleared under premarket notification K120414.

Biocompatibility Testing:

Biocompatibility evaluation assessment for the PrimeTaper EV Dental Implants has been made according to *ISO 10993-1 - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*. The subject devices have the same nature of body contact, contact duration, material and sterilization method compared to the predicate device.

Fatigue Testing:

Dynamic fatigue testing was conducted on the worst-case implant – abutment combination of the subject and predicate devices according to *ISO 14801 Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants*. The comparative testing demonstrates that the subject implants do not create a new worst-case as compared to the predicate device with identical connection platform. The tests were performed to evaluate the fatigue load limits of the proposed PrimeTaper EV Dental Implants. The results support the substantial equivalence of the proposed PrimeTaper EV devices to the predicate device (K120414).

Shelf Life Testing:

The shelf-life for the proposed PrimeTaper EV Dental Implant is five years. The packaging materials and configuration for the proposed PrimeTaper EV Dental Implant are the same as used for the packaging of the predicate device OsseoSpeed Plus Implant (K120414). Therefore, no new validation of shelf life has been conducted to support substantial equivalence in this premarket notification.

For products supplied sterile, a LAL test is conducted periodically to verify the endotoxin limit is within acceptance criteria according to USP 85, USP 161 and ANSI/AAMI/ ST72.

Surface Area Comparison

Surface area analysis using CAD software was performed with the PrimeTaper EV Implant with the smallest diameter and the shortest length (PrimeTaper EV D 4.2/ L 6.5 mm) and compared to the predicate implant OsseoSpeed™ EV 4.2 S - 6 mm Implant (K120414) with the same diameter and similar length, to determine if the endosseous area that contacts bone of both implants is equivalent.

The surface area of the PrimeTaper EV short implant that contacts bone is equivalent to the predicate device OsseoSpeed EV with similar length and identical diameter. Therefore, the amount of bone to implant contact of PrimeTaper EV Ø4.2 x 6.5mm is equivalent to the predicate device OsseoSpeed EV 4.2 S - 6 mm Implant.

Installation Torque Test:

Installation torque tests were conducted with the proposed PrimeTaper EV implants to evaluate the installation properties of the implants.

In *in vitro* studies, the installation performance of the PrimeTaper EV Implants was investigated in different artificial bone models, simulating various bone densities and extraction sites and compared to the predicate device OsseoSpeed Plus Implant (K120414). Implant site preparation and implant insertion was performed following the surgical protocols of the respective implant system as described in the Instructions for Use. With these tests, it was demonstrated that the PrimeTaper EV Implants perform as intended and support substantial equivalence of the proposed PrimeTaper EV Implant to the predicate device OsseoSpeed™ Plus implant.

5.8 Clinical Performance Data

Clinical data was included in this premarket notification to support the performance equivalence of short OsseoSpeed implants (6 mm length) in comparison to "standard-length" OsseoSpeed implants:

- Thoma et.al. investigated short (6 mm) OsseoSpeed implants vs standard length implants in combination with bone augmentation in the posterior maxilla, restored with single crowns and followed-up for 5 years. This study showed no differences in terms of survival rates, marginal bone levels changes, patient-reported outcomes and technical or biological complications between short and standard length implants[1].
- Guljé et.al. compared 6 mm OsseoSpeed implants to 11 mm OsseoSpeed implants in the posterior maxilla or mandible, using a one-stage surgical approach with an early loading protocol. They found no significant difference in implant survival rate, marginal bone level alterations, soft tissue parameters or complications between the short implants group and the group with longer implants after 5 years[2].

The above prospective, randomized, controlled studies show that both treatment modalities i.e. short implants and standard-length implants, are suitable for implant therapy in both the maxilla and the mandible, with no significant differences in terms of survival rates, marginal bone level changes, patient-reported outcomes and technical/biological complications.

Clinical data was included in this premarket notification to support performance equivalence of the proposed PrimeTaper EV implants with the predicate OsseoSpeed Plus Implants for long-term bone preservation:

A summary of published, prospective studies available on OsseoSpeed Plus implants, where long-term bone preservation is evaluated below:

- Cooper et. al. evaluated OsseoSpeed implants, in a long-term, prospective follow-up study with immediate loading in both healed ridges and extraction sockets. 113 implants/subjects were included. The results show stable marginal bone levels (bone preservation), high survival rates and stable soft tissue levels after 5 years in function[3].
- Donati et. al. published a 5-year, prospective, multicenter study with 151 subjects on OsseoSpeed implants evaluating marginal bone preservation after single-tooth replacement. The results show minimal levels of bone loss and even a bone gain in 50% of the implants evaluated[4].

- Norton et. al. published a systematic review and meta-analysis comparing marginal bone levels between three premium implant brands, OsseoSpeed (Astra Tech Implant System), TiUnite (Nobel Biocare) and SLA/SLActive (Straumann). At the 1-year follow-up, data were available for 2,586 implants for Astra Tech Implant System, compared with 1,490 and 3,948 implants for Straumann and Nobel Biocare, respectively. After 1- and 5-year follow-ups, there was a statistically significant difference between the three implant brands, with the OsseoSpeed implant showing superior marginal bone maintenance, with stable long-term bone preservation[5].
- Windael et. al evaluated immediately loaded OsseoSpeed implants in 25 patients, placed in the edentulous mandible, in a prospective clinical study with a 10-year follow-up. The results show an implant survival rate of 100%, and 47% of the implants did not show any bone loss after 10 years and 87% lost less than 1 mm bone i.e. the marginal bone was preserved after 10 years in function[6].

In conclusion, the above prospective, clinical studies with a follow-up time of up to 10 years show that the OsseoSpeed Plus implants provide long-term bone preservation, high survival rates and stable soft tissue levels in different clinical situations; in the maxilla and the mandible, in extraction sockets and healed ridges, restored with single implants or bridges and with different loading protocols.

References:

1. Thoma DS, Haas R, Sporniak-Tutak K, Garcia A, Taylor TD, Hammerle CHF. Randomized controlled multicentre study comparing short dental implants (6 mm) versus longer dental implants (11-15 mm) in combination with sinus floor elevation procedures: 5-Year data. J Clin Periodontol 2018;45(12):1465-74.
2. Gulje FL, Meijer HJA, Palmer PJ, Abrahamsson I, Chen S, Zadeh H, Barwacz CA, Stanford CM. Comparison of 6-mm and 11-mm dental implants in the posterior region supporting fixed dental prostheses; 5-year results of an open multi-center randomized controlled trial. Clin Oral Implants Res 2020;E-pub Oct 8 doi:10.1111/clr.13674.
3. Cooper LF, Reside GJ, Raes F, Garriga JS, Tarrida LG, Wiltfang J, Kern M, De Bruyn H. Immediate provisionalization of dental implants placed in healed alveolar ridges and extraction sockets: A 5-year prospective evaluation. Int J Oral Maxillofac Implants 2014;29(3):709-17
4. Donati M, La Scala V, Di Raimondo R, Speroni S, Testi M, Berglundh T. Marginal bone preservation in single-tooth replacement: a 5-year prospective clinical multicenter study. Clin Implant Dent Relat Res 2015;17(3):425-34
5. Norton MR, Astrom M. The Influence of Implant Surface on Maintenance of Marginal Bone Levels for Three Premium Implant Brands: A Systematic Review and Meta-analysis. Int J Oral Maxillofac Implants 2020;35(6):1099-111
6. Windael S, Vervaeke S, Wijnen L, Jacquet W, De Bruyn H, Collaert B. Ten-year follow-up of dental implants used for immediate loading in the edentulous mandible: A prospective clinical study. Clin Implant Dent Relat Res 2018;20(4):515-21

5.9 Conclusion Regarding Substantial Equivalence

The subject device PrimeTaper EV Dental Implants are endosseus dental implants which are intended to be used by dental clinicians for prosthetic restoration in the maxilla and mandible. The proposed devices incorporate the same fundamental technology and intended use as the predicate device and have similar indications for use.

Non-clinical bench testing has been conducted and included in this premarket notification to demonstrate the performance of the proposed PrimeTaper EV Dental Implants against their design, functional and safety requirements. The comparison of the indications for use, technological

characteristics, and the results of nonclinical testing, support substantial equivalence of the proposed PrimeTaper EV Dental Implants to the predicate device and reference device.