April 30, 2025

Dentsply Sirona
Laura Sobrin
Sr. Technical RA Manager
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K250295
Trade/Device Name: Dentsply Sirona Titanium Bases system
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: January 31, 2025
Received: January 31, 2025

Dear Laura Sobrin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

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

510(k) Number *(if known)*
K250295

Device Name
Dentsply Sirona Titanium Bases system

Indications for Use *(Describe)*
The Dentsply Sirona Titanium Bases system is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

For AT EV 3.0 S, AT TX 3.0 S, BH 3.0 S, and SB L 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.

The system comprises three parts:
• Abutment Block material (CEREC Cercon 4D Abutment Block)
• Titanium Base (TiBase)
• CAD/CAM system
The TiBase is recommended for use with two-piece hybrid abutments and hybrid abutment crowns, used in conjunction with endosseous dental implants.

Implant Systems:
- Dentsply Sirona: AstraTech Implant EV, PrimeTaper EV, OmniTaper EV, Astra Tech OsseoSpeed TX, Ankylos
- BioHorizons: Internal connection
- Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Conical Connection, Brånemark, NobelSpeedy Groovy
- Osstem/Hiossen: Osstem TS, USA: Hiossen ET
- Straumann: Bone Level, Tissue Level
- Thommen Medical: Element, Contact
- Zimmer/Biomet: Certain, External hex, Tapered Screw-Vent

CAD/CAM Systems:
- Sirona Dental CAD/CAM System

Platforms:
Manufacturer: Dentsply Sirona
Implant: Astra Tech Implant EV, PrimeTaper EV, OmniTaper EV
Platform: XS; TiBase AT EV 3.0 GH1 S; Reference: 6586304; Size S
Platform: S; TiBase AT EV 3.6 GH1 S; Reference: 6586312; Size: S
Platform: M; TiBase AT EV 4.2 GH1 L; Reference: 6586320; Size: L
Platform: L; TiBase AT EV 4.8 GH1 L; Reference: 6586338; Size: L
Platform: XS; TiBase AT EV 3.0 GH2 S; Reference: 6832575; Size S
Platform: S; TiBase AT EV 3.6 GH2 S; Reference: 6832583; Size: S
Platform: M; TiBase AT EV 4.2 GH2 L; Reference: 6832591; Size: L
Platform: L; TiBase AT EV 4.8 GH2 L; Reference: 6832609; Size: L
Platform: XS; TiBase AT EV 3.0 GH3 S; Reference: 6832625; Size S
Platform: S; TiBase AT EV 3.6 GH3 S; Reference: 6832633; Size: S
Platform: M; TiBase AT EV 4.2 GH3 L; Reference: 6832641; Size: L
Platform: L; TiBase AT EV 4.8 GH3 L; Reference: 6832658; Size: L

Manufacturer: Dentsply Sirona

Implant: Astra Tech Implant EV, OmniTaper EV
Platform: XL; TiBase AT EV 5.4 GH1 L; Reference: 6586346; Size: L
Platform: XL; TiBase AT EV 5.4 GH2 L; Reference: 6832617 Size: L
Platform: XL; TiBase AT EV 5.4 GH3 L; Reference: 6832666; Size: L

Manufacturer: Dentsply Sirona
Implant: Astra Tech OsseoSpeed TX
Platform 3.0; TiBase AT TX 3.0; Reference: 6598085; Size: S
Platform 3.5 / 4.0; TiBase AT TX 3.5/4.0 L; Reference: 6598093; Size: L
Platform 4.5 / 5.0; TiBase AT TX 4.5/5.0 L; Reference: 6598101; Size: L

Manufacturer: Dentsply Sirona
Implant: Ankylos
Platform: C/X; TiBase ANK C/ GH 1 S; Reference: 6586528; Size: S
Platform: C/X; TiBase ANK C/ GH 2 S; Reference: 6586536; Size: S
Platform: C/X; TiBase ANK /X GH 1 S; Reference: 6586544; Size: S
Platform: C/X; TiBase ANK /X GH 2 S; Reference: 6586551; Size: S

Manufacturer: BioHorizons
Implant: Internal Connection
Platform: 3.0; TiBase BH 3.0 S; Reference: 6532779; Size: S
Platform: 3.5; TiBase BH 3.5 L; Reference: 6532894; Size: L
Platform: 4.5; TiBase BH 4.5 L; Reference: 6532951; Size: L
Platform: 5.7; TiBase BH 5.7 L; Reference: 6536242; Size: L

Manufacturer: Nobel Biocare
Implant: Replace, Replace Select
Platform: NP; TiBase NB RS 3.5 L; Reference: 6282474; Size: L
Platform: RP; TiBase NB RS 4.3 L; Reference: 6282482; Size: L
Platform: WP; TiBase NB RS 5.0 L; Reference: 6282490; Size: L
Platform: 6.0; TiBase NB RS 6.0 L; Reference: 6282508; Size: L

Manufacturer: Nobel Biocare
Implant: Nobel Active, NobelReplace Conical Connection
Platform: NP; TiBase NB A 4.5 L; Reference: 6308188; Size: L
Platform: RP; TiBase NB A 5.0 L; Reference: 6308253; Size: L

Manufacturer: Nobel Biocare
Implant: Brånemark, NobelSpeedy Groovy
Platform: NP, TiBase NB B 3.4 L; Reference: 6282516; Size: L
Platform: RP; TiBase NB B 4.1 L; Reference: 6282524; Size: L

Manufacturer: Osstem / Hiossen
Implant: Osstem TS (US Hiossen ET)
Platform: Mini; TiBase O TS 3.5 L; Reference: 6527035; Size: L
Platform: Regular; TiBase O TS 4.0 L; Reference: 6527043; Size: L

Manufacturer: Straumann
Implant: Bone Level
Platform: NC (3.3 mm); TiBase S BL 3.3 L; Reference: 6308154; Size: L
Platform: RC (4.1 mm / 4.8 mm); TiBase S BL C 4.1 L; Reference: 6308337; Size: L

Manufacturer: Straumann
Implant: Tissue Level

Platform: RN (4.8 mm); TiBase S SO 4.8 L; Reference: 6284249; Size: L
Platform: WN (6.5 mm); TiBase S SO 6.5 L; Reference: 6284256; Size: L

Manufacturer: Thommen Medical
Implant: Element, Contact
Platform: 3.5; TiBase TM 3.5 S; Reference: 6531854; Size: S
Platform: 4; TiBase TM 4 S; Reference: 6532829; Size: S
Platform: 4.5; TiBase TM 4.5 S; Reference: 6532837; Size: S
Platform: 5; TiBase TM 5 S; Reference: 6544360; Size: S
Platform: 6; TiBase TM 6 S; Reference: 6544378; Size: S

Manufacturer: Zimmer / Biomet
Implant: Certain
Platform: 3.4; TiBase B C 3.4 S; Reference: 6308048; Size: S
Platform: 4.1; TiBase B C 4.1 L; Reference: 6308097; Size: L
Platform: 5.0; TiBase B C 5.0 L; Reference: 6308121; Size: L

Manufacturer: Zimmer / Biomet
Implant: External hex
Platform: 3.4; TiBase B O 3.4 L; Reference: 6282557; Size: L
Platform: 4.1; TiBase B O 4.1 L; Reference: 6282565; Size: L
Platform: 5.0; TiBase B O 5.0 L; Reference: 6282573; Size: L

Manufacturer: Zimmer / Biomet
Implant: Tapered Screw-Vent
Platform: 3.5; TiBase Z TSV 3.5 L; Reference: 6282581; Size: L
Platform: 4.5; TiBase Z TSV 4.5 L; Reference: 6282599; Size: L
Platform: 5.7; TiBase Z TSV 5.7 L; Reference: 6282607; Size: L

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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510(k) SUMMARY
for
Dentsply Sirona Titanium Bases system (K250295)

1. Submitter Information:

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

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Email: laura.sobrin@dentsplysirona.com

Date Prepared: April 29, 2025

2. Device Name:

- Proprietary Name: Dentsply Sirona Titanium Bases system
- Classification Name: Abutment, Implant, Endosseous, Root-Form
- CFR Number: 872.3630
- Device Class: Class II
- Primary Product Code: NHA
- Secondary Product Code: PNP

3. Predicate/Reference Devices:

The submission proposes to add new TiBase components compatible with the CEREC Cercon 4D Abutment Block (K234018), which is the material that forms the top-half of a two-piece abutment. Furthermore, this submission also proposes to update the safety in an MR environment to indicate MR Conditional for both the predicate device TiBases system (K193408) and the line extension TiBases system, which share the same labeling. In addition, the CEREC Cercon 4D Abutment Block (K234018) replaces the inCoris Zi meso (K111421) in the TiBase system workflow as the top-half material. As a result of this change, the Indications for Use, which describe the workflow of the TiBase system, are also modified.

Table 3.1: Predicate device information			
Predicate Device Name	**510(k)**	**Product Code and Classification Reg**	**Company Name**
Sirona Dental CAD/CAM System with CEREC Chairside Software	K193408	21 CFR 872.3630 NHA, PNP	Dentsply Sirona Inc.

Table 3.2: Reference device information				
Reference Device Name	**510(k)**	**Product code and Regulation #**	**Company Name**	**Reason for Inclusion**
Sirona Dental CAD/CAM System with inLab Software	K200191	21 CFR 872.3630 PNP	Dentsply Sirona Inc.	The TiBases are also integrated into the inLab CAD/CAM system, where the user can design and mill the top half of the abutment.
CEREC Cercon 4D Abutment Blocks, CEREC Abutment 4D Abutment System	K234018	21 CFR 872.3630 NHA	Dentsply Sirona Inc.	This submission cleared compatibility of the CEREC Cercon 4D with the predicate TiBases (K193408), effectively replacing the inCoris Zi meso material (K111421) which is discontinued. Reprocessing and biocompatibility testing performed on predicate device TiBases (K193408) with these block materials, is included by reference.
TruBase	K213961	21 CFR 872.3630 NHA	TruAbutment Inc.	This submission cleared TiBases with similar technological characteristics and same implant connection as the proposed TiBases. Fatigue testing is included to support substantial equivalence.
TruBase	K241485	21 CFR 872.3630 NHA	TruAbutment Inc.	This submission cleared TiBases with similar technological characteristics and same implant connection as the proposed TiBases. Fatigue testing is included to support substantial equivalence.
PrimeTaper EV Implant System	K220841	21 CFR 872.3640 DZE	Dentsply Sirona Inc.	MR Conditional testing included in K220841 also supports the change from MR Not Evaluated to MR Conditional for the TiBases subject of this submission.

Additional devices referenced in the performance testing section to support the fatigue testing plan and results, including historical fatigue data, are listed below.

Table 3.3: Additional reference devices to support performance testing section				
Reference Device Name	**510(k)**	**Product code and Regulation #**	**Company Name**	**Reason for Inclusion**
inCoris Zi	K123664	EIH, 872.6660	Sirona Dental Systems GmbH (now part of Dentsply Sirona)	The reference devices, TruBase (K213961, K241485) were cleared for use with this top-half material. This material is included in the discussion in the Performance section of this submission.
inCoris Zi meso blocks (part of Sirona CAD/CAM System)	K111421	NHA, 872.3630	Sirona Dental Systems GmbH (now part of Dentsply Sirona)	The material is cleared for use together with the predicate device TiBases (K193408). This material is included in the discussion in the Performance section of this submission.

4. Description of Device:

The proposed Dentsply Sirona Titanium Bases system are connected to Dentsply Sirona or third-party dental implants to facilitate the prosthetic dental restoration of edentulous areas of the oral anatomy. The proposed TiBase components are assembled (through extraoral cement bonding) with the patient specific CEREC Cercon 4D Abutment Block (K234018), to form the complete, two-piece CAD/CAM Titanium Base system abutments. The bottom half of the abutment is the TiBase component, which interfaces with the implant system-specific geometry, while the top half of the abutment is the abutment block material that is milled to form either an abutment crown or a meso-structure (the latter is subsequently finished with a crown). The TiBase component therefore serves as the "platform" on which the customized milled abutment crown or the meso-structure is bonded to, forming the complete CAD/CAM Titanium Base system abutment. The completed CAD/CAM Titanium Base system abutment is attached to the dental implant with an abutment screw.

The TiBase system is part of a workflow that includes CAD/CAM software cleared in predicate device, K193408, CAD/CAM system with CEREC Chairside Software, and reference device, K200191, CAD/CAM System with inLab Software, and the abutment crown and meso-structure material cleared in reference device, K234018.

The TiBase components are made of the same material as the predicate device (K193408) TiBases, which is titanium alloy Ti6Al4V, complying with ASTM F136-13. While the lower part connects to the implant system, the upper part consists of a tapered, cylindrical center post which is designed to receive the abutment crown or meso-structure to complete the finished CAD/CAM abutment.

The TiBase components come in small and large sizes depending on the diameter size of the connecting implant. A notch feature on the cylindrical part of the upper portion (i.e. rotational reference and lock) ensures that there is only one position to mount either a scanbody or the abutment crown/meso-structure.

The TiBase component center post includes a through-channel through which a corresponding abutment screw is inserted to allow retention of the finished abutment to the implant. The abutment screw, made of the same Titanium material, when assembled with

the proposed TiBase component, is located in the internal geometry of the titanium base and does not seat in the finalized abutment crown/meso-structure.

The minimum/maximum design specification limits are as follows:

- Maximum angulation for the Zirconia top-half material: 20˚
- Minimum wall thickness of the Zirconia top-half material: 0.5 mm
- Gingival heights of the TiBase component: 1, 2, 3 mm
- TiBase component post height (i.e., length above the gingival height): ≥ 4 mm

5. Intended Use and Indications for Use:

The proposed TiBases systems have the same intended use as the predicate device, K193408. The TiBases systems are intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations, in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity.

The predicate device has a wider intended use for multiple-unit cement retained restorations which no longer applies to the proposed TiBases systems.

Table 5: Comparison between Indications for Use of the Proposed Device and the Predicate Device

Table 5 - Comparison of Indications for Use		
Proposed Device	**Predicate Device (K193408)**	**Discussion**
The Dentsply Sirona Titanium Bases system is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. For AT EV 3.0 S, AT TX 3.0 S, BH 3.0 S, and SB L 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system comprises three parts: • Abutment Block material (CEREC Cercon 4D Abutment Block) • Titanium Base (TiBase) • CAD/CAM system The TiBase is recommended for use with two-piece hybrid abutments and hybrid abutment crowns, used in conjunction with endosseous dental implants.	The Sirona Dental CAD/CAM System with CEREC Chairside Software is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the AT TX 3.0 S, BH 3.0 S, SSO 3.5 L, and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two- piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.XXXX) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:	Similar. The TiBases in the proposed and predicate devices are the bottom half of a two-piece abutment and are intended to be used with a top half abutment block material in conjunction with CAD/CAM software to design and manufacture an abutment. Therefore, the indicated workflow is the same. The submission is specific to the TiBases and therefore the proposed indications do not include the CAD/CAM software specific indications. In addition, inCoris Zi mesostructure material (now discontinued) was replaced with the CEREC Cercon 4D (K234018) abutment block materials. This abutment block material is only indicated for single cement retained restorations and therefore the TiBase indications are narrower in scope compared to the

<table>
<tr><th colspan="3"><u>Table 5</u> - Comparison of Indications for Use</th></tr>
<tr><th>Proposed Device</th><th>Predicate Device
(K193408)</th><th>Discussion</th></tr>
<tr><td></td><td></td><td>predicate device, which included multiple-unit cement retained restorations. The statements in the proposed indications align with this compatible abutment block material.

The Straumann Standard Tissue Level, SSO 3.5 L TiBase is discontinued and therefore removed from the restrictions for use. The restrictions for use on the AT EV 3.0 S was added as this is one of the TiBases proposed to be cleared in this submission.</td></tr>
<tr><td>Implant Systems:
▪ Dentsply Sirona: AstraTech Implant EV, PrimeTaper EV, OmniTaper EV, AstraTech OsseoSpeed TX, Ankylos
▪ BioHorizons: Internal connection
▪ Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Conical Connection, Brånemark, NobelSpeedy Groovy
▪ Osstem/Hiossen: Osstem TS, USA: Hiossen ET
▪ Straumann: Bone Level, Tissue Level
▪ Thommen Medical: Element, Contact
▪ Zimmer/Biomet: Certain, External hex, Tapered Screw-Vent

CAD/CAM Systems:
▪ Sirona Dental CAD/CAM System</td><td><table>
<tr><th rowspan="2">Manufacturer</th><th rowspan="2">Name of Implant System</th><th colspan="2">Implant Size</th></tr>
<tr><th>Platform</th><th>Diameter</th></tr>
<tr><td rowspan="8">Nobel Biocare</td><td rowspan="4">Replace</td><td>NP</td><td>3.5</td></tr>
<tr><td>RP</td><td>4.3</td></tr>
<tr><td>WP</td><td>5.0</td></tr>
<tr><td>6.0</td><td>6.0</td></tr>
<tr><td rowspan="2">Active</td><td>NP</td><td>3.5</td></tr>
<tr><td>RP</td><td>4.3/5.0</td></tr>
<tr><td rowspan="2">Branemark</td><td>NP</td><td>3.3</td></tr>
<tr><td>RP</td><td>3.75/4.0</td></tr>
<tr><td rowspan="4">Straumann</td><td rowspan="2">Synocta</td><td>RN (4.8mm)</td><td>3.3/4.1/4.8</td></tr>
<tr><td>WN (6.5mm)</td><td>4.8</td></tr>
<tr><td rowspan="2">Bone Level</td><td>NC (3.3mm)</td><td>3.3</td></tr>
<tr><td>RC (4.1mm/ 4.8mm)</td><td>4.1/4.8</td></tr>
</table></td><td>Same compatible implant systems but with the following modifications:
- Added new TiBases with gingiva heights 2 and 3 mm, compatible with the EV conical connection implants
- Added TiBase with 3.0 diameter and gingiva height 1 mm, compatible with the EV conical connection implants
- Added reference to the OmniTaper EV and PrimeTaper EV implant systems. These implant systems share the same EV</td></tr>
</table>

Table 5 - Comparison of Indications for Use

Proposed Device	Predicate Device (K193408)				Discussion
Platforms: Manufacturer: Dentsply Sirona Implant: Astra Tech Implant EV, PrimeTaper EV, OmniTaper EV Platform: XS; TiBase AT EV 3.0 GH1 S; Reference: 6586304; Size S Platform: S; TiBase AT EV 3.6 GH1 S; Reference: 6586312; Size: S Platform: M; TiBase AT EV 4.2 GH1 L; Reference: 6586320; Size: L Platform: L; TiBase AT EV 4.8 GH1 L; Reference: 6586338; Size: L Platform: XS; TiBase AT EV 3.0 GH2 S; Reference: 6832575; Size S Platform: S; TiBase AT EV 3.6 GH2 S; Reference: 6832583; Size: S Platform: M; TiBase AT EV 4.2 GH2 L; Reference: 6832591; Size: L Platform: L; TiBase AT EV 4.8 GH2 L; Reference: 6832609; Size: L Platform: XS; TiBase AT EV 3.0 GH3 S; Reference: 6832625; Size S Platform: S; TiBase AT EV 3.6 GH3 S; Reference: 6832633; Size: S Platform: M; TiBase AT EV 4.2 GH3 L; Reference: 6832641; Size: L Platform: L; TiBase AT EV 4.8 GH3 L; Reference: 6832658; Size: L Manufacturer: Dentsply Sirona Implant: Astra Tech Implant EV, OmniTaper EV Platform: XL; TiBase AT EV 5.4 GH1 L; Reference: 6586346; Size: L Platform: XL; TiBase AT EV 5.4 GH2 L; Reference: 6832617 Size: L Platform: XL; TiBase AT EV 5.4 GH3 L; Reference: 6832666; Size: L Manufacturer: Dentsply Sirona Implant: Astra Tech OsseoSpeed TX Platform 3.0; TiBase AT TX 3.0; Reference: 6598085; Size: S Platform 3.5 / 4.0; TiBase AT TX 3.5/4.0 L; Reference: 6598093; Size: L Platform 4.5 / 5.0; TiBase AT TX 4.5/5.0 L; Reference: 6598101; Size: L Manufacturer: Dentsply Sirona Implant: Ankylos Platform: C/X; TiBase ANK C/ GH 1 S; Reference: 6586528; Size: S Platform: C/X; TiBase ANK C/ GH 2 S; Reference: 6586536; Size: S Platform: C/X; TiBase ANK /X GH 1 S; Reference: 6586544; Size: S Platform: C/X; TiBase ANK /X GH 2 S; Reference: 6586551; Size: S Manufacturer: BioHorizons Implant: Internal Connection Platform: 3.0; TiBase BH 3.0 S; Reference: 6532779; Size: S					conical connection as the Astra Tech EV implant system. - TiBases (FX and AT OS) are discontinued and therefore removed from the proposed indications. - Minor modification to implant system naming conventions to align with the top-half material (K234018) compatibility table - "Synocta" implant was replaced with "Tissue Level" implant which refers to the same implant system. Similarly, "Osseotite" was replaced with "External hex", which are the same implant system. The naming convention of these implant systems is consistent with the top-half material (K234018) Indications for Use.
	Dentsply Sirona Implants	Osseospeed	3.5/4.0	3.5 S / 4.0 S	
			4.5/5.0	4.5/5.0/5.0 S	
		Xive	3.4	3.4	
			3.8	3.8	
			4.5	4.5	
			5.5	5.5	
		Osseospeed EV	3.6	3.6	
			4.2	4.2	
			4.8	4.8	
			5.4	5.4	
		Ankylos	C/X	A, B, C, D	
		Osseospeed TX	3.0	3.0	
			3.5/4.0	3.5/4.0	
			4.5/5.0	4.5/5.0	
	Biomet 3i	Osseotite	3.4	3.25	
			4.1	3.75	
				4.1	
				3/4	
			5.0	5.0	
				4/5	
		Certain	3.4	3.25	
				4/3	
				3/4/3	
			4.1	4.0	
				4/5/4	
				5/4	
			5.0	5.0	
				4/5	
	Zimmer	Tapered Screw-Vent	3.5	3.7/4.1	
			4.5	4.7	
			5.7	6	
	Thommen	Thommen	3.5	3.5	
			4	4	
			4.5	4.5	
			5	5	

Table 5 - Comparison of Indications for Use

Proposed Device	Predicate Device (K193408)				Discussion
Platform: 3.5; TiBase BH 3.5 L; Reference: 6532894; Size: L Platform: 4.5; TiBase BH 4.5 L; Reference: 6532951; Size: L Platform: 5.7; TiBase BH 5.7 L; Reference: 6536242; Size: L Manufacturer: Nobel Biocare Implant: Replace, Replace Select Platform: NP; TiBase NB RS 3.5 L; Reference: 6282474; Size: L Platform: RP; TiBase NB RS 4.3 L; Reference: 6282482; Size: L Platform: WP; TiBase NB RS 5.0 L; Reference: 6282490; Size: L Platform: 6.0; TiBase NB RS 6.0 L; Reference: 6282508; Size: L Manufacturer: Nobel Biocare Implant: Nobel Active, NobelReplace Conical Connection Platform: NP; TiBase NB A 4.5 L; Reference: 6308188; Size: L Platform: RP; TiBase NB A 5.0 L; Reference: 6308253; Size: L Manufacturer: Nobel Biocare Implant: Brånemark, NobelSpeedy Groovy Platform: NP, TiBase NB B 3.4 L; Reference: 6282516; Size: L Platform: RP; TiBase NB B 4.1 L; Reference: 6282524; Size: L Manufacturer: Osstem / Hiossen Implant: Osstem TS (US Hiossen ET) Platform: Mini; TiBase O TS 3.5 L; Reference: 6527035; Size: L Platform: Regular; TiBase O TS 4.0 L; Reference: 6527043; Size: L Manufacturer: Straumann Implant: Bone Level Platform: NC (3.3 mm); TiBase S BL 3.3 L; Reference: 6308154; Size: L Platform: RC (4.1 mm / 4.8 mm); TiBase S BL C 4.1 L; Reference: 6308337; Size: L Manufacturer: Straumann Implant: Tissue Level Platform: RN (4.8 mm); TiBase S SO 4.8 L; Reference: 6284249; Size: L Platform: WN (6.5 mm); TiBase S SO 6.5 L; Reference: 6284256; Size: L Manufacturer: Thommen Medical	Medical	Medical Implants	6	6	
	Osstem / Hiossen	Osstem TS Implant System Hiossen Implant System	Mini	3.5	
			Regular	4.0/4.5/5.0/ 6.0/7.0	
	BioHorizons (Internal Connection)	Tapered 3.0,Tapered plus	3.0	3.0/3.4/3.8	
		Tapered internal		3.0	
		Tapered plus	3.5	4.6	
		Tapered internal, Tapered internal tissue level		3.0/3.8	
		Internal dental implant		3.5	
		Single stage dental implants		3.5/4.0	
		Tapered Plus	4.5	5.8	
		Tapered internal, Tapered internal tissue level		4.6	
		Internal dental implant		4.0	
		Single stage dental		4.0/5.0	

Table 5 - Comparison of Indications for Use				
Proposed Device	**Predicate Device (K193408)**			**Discussion**
Implant: Element, Contact Platform: 3.5; TiBase TM 3.5 S; Reference: 6531854; Size: S Platform: 4; TiBase TM 4 S; Reference: 6532829; Size: S Platform: 4.5; TiBase TM 4.5 S; Reference: 6532837; Size: S Platform: 5; TiBase TM 5 S; Reference: 6544360; Size: S Platform: 6; TiBase TM 6 S; Reference: 6544378; Size: S Manufacturer: Zimmer / Biomet Implant: Certain Platform: 3.4; TiBase B C 3.4 S; Reference: 6308048; Size: S Platform: 4.1; TiBase B C 4.1 L; Reference: 6308097; Size: L Platform: 5.0; TiBase B C 5.0 L; Reference: 6308121; Size: L Manufacturer: Zimmer / Biomet Implant: External hex Platform: 3.4; TiBase B O 3.4 L; Reference: 6282557; Size: L Platform: 4.1; TiBase B O 4.1 L; Reference: 6282565; Size: L Platform: 5.0; TiBase B O 5.0 L; Reference: 6282573; Size: L Manufacturer: Zimmer / Biomet Implant: Tapered Screw-Vent Platform: 3.5; TiBase Z TSV 3.5 L; Reference: 6282581; Size: L Platform: 4.5; TiBase Z TSV 4.5 L; Reference: 6282599; Size: L Platform: 5.7; TiBase Z TSV 5.7 L; Reference: 6282607; Size: L		implants		
		Tapered internal, Tapered internal tissue level	5.7	5.8
		Internal dental implant, Single stage dental implants		5.0/6.0

6. Technological Comparison:

The proposed TiBase components and corresponding screws are made of the same materials, manufactured using the same processes, and packaged using the same materials and processes as the predicate device TiBases (K193408). In addition, the proposed and predicate devices share the same design and manufacturing workflow using the CAD/CAM system CEREC Chairside (K193408) and inLab (K200191) for design and milling of the top-half of the abutment.

The modifications to the predicate device TiBase system workflow consist of obsoleting the inCoris Zi meso material as the top-half material, and replacing with the CEREC Cercon 4D material, as cleared in K234018. Fatigue testing submitted in the reference device submission, CEREC Cercon 4D abutment block material (K234018), cleared the use of the predicate device TiBases system (K193408) together with the abutment block material. In addition, the cement proposed in the workflow to bond the milled block materials to the TiBase component matches the cement used in the fatigue testing included in K234018 as well as the fatigue testing included in this submission. In short, the predicate device TiBases system (K193408) specified Panavia F 2.0 adhesive on the labeling which has now been modified to match the cement that is used with the CEREC Cercon 4D abutment block material (K234018), the Calibra Abutment Resin Cement (K240888).

In addition, new TiBases systems compatible with the EV conical connection for gingival heights 2 and 3 mm are introduced for existing Dentsply Sirona EV implant connections (AstraTech EV, OmniTaper EV, and PrimeTaper EV implant systems). The predicate device TiBases systems (K193408) are already cleared for compatibility with EV connections (at gingival height 1 mm). Moreover, 2 mm gingival height TiBase components are also available with the predicate device TiBases systems (K193408), compatible with the Ankylos implant system. The 3 mm gingival height option is within the range of the 2.8 and 3.8 mm gingival height offered with the reference devices, TruBase (K213961, K241485). The TruBase abutments (K213961, K241485) are also compatible with the Dentsply Sirona EV conical connection implants. As the 3 mm gingival height is a new height for Dentsply Sirona TiBase components, fatigue testing was performed to ensure that any differences in gingival height do not raise new questions regarding safety and performance.

Compatibility of the predicate device, AstraTech TX 3.0 TiBase (K193408) with the CEREC Cercon 4D (K234018) abutment block material is also added as part of this submission. Fatigue testing discussion is included to demonstrate that this additional compatibility does not raise new questions regarding safety and performance.

Furthermore, reprocessing instructions for the proposed TiBases systems were updated to point to the Instructions for Use of the CEREC Cercon 4D (K234018) reference device material, which is part of the same CAD/CAM workflow, and also manufactured by Dentsply Sirona. The reprocessing validation provided in the abutment block submission (K234018) is included by reference in this submission.

Table 6 below provides a comparison of the technological characteristics between the proposed device, the predicate device (K193408) and the reference devices, TruBase (K213961, K241485).

Table 6: Comparison between the proposed TiBases, predicate device (K193408) TiBases, and reference device, TruBase (K213961, K241485)				
Item of Comparison	**Proposed Device TiBases**	**Predicate Device TiBases (K193408)**	**Reference Devices TruBase (K213961, K241485)**	**Similarities and Differences**
Product Code	NHA, PNP	NHA, PNP	NHA	Same as predicate device
Manufacturer	Dentsply Sirona	Dentsply Sirona	TruAbutment Inc.	Same as predicate device
TiBase Component Material	Titanium alloy (Ti6Al4V)	Titanium alloy (Ti6Al4V)	Titanium alloy (Ti6Al4V)	Same
Compatible Implant Diameter range	3.0 – 6.5 mm	3.0 mm – 7.0 mm	3.0 mm – 7.0 mm	Within range of the predicate and reference devices
Compatible Implant Systems	• Dentsply Sirona Astra Tech OsseoSpeed TX, Astra Tech Implant EV , PrimeTaper EV, OmniTaper EV, Ankylos • BioHorizons • NobelBiocare Replace, Replace Select, Nobel Active, NobelReplace Conical Connection, Branemark, NobelSpeedy Groovy	• Dentsply Sirona Astra Tech OsseoSpeed TX, XiVE, Astra Tech Implant EV, Ankylos, OsseoSpeed • BioHorizons • NobelBiocare Replace/Replace Select, Nobel Active/Nobel Replace Conical Connection, Branemark/NobelSpeedy Groovy	• Osstem TS III SA • Astra Tech OsseoSpeed EV • BioHorizons Tapered Internal • Straumann Tissue Level • Biomet 3i Full OSSEOTITE Tapered Certain • D1O UF(II) Internal Submerged (Narrow, Regular)	Same as the predicate device except for cross-reference to the PrimeTaper EV (K210610, K220841) and OmniTaper EV (K221094) implant systems. The Astra Tech EV implant system has the same EV conical connection as the PrimeTaper and OmniTaper EV implant systems and therefore share the same TiBases. The TruBase reference devices (K213961, K241485) are also compatible with the AstraTech EV implant system and fatigue testing is included in the submission to support the new gingival heights for the EV conical connection implant systems. Some implant systems have been removed and therefore no longer on the compatibility chart.

Table 6: Comparison between the proposed TiBases, predicate device (K193408) TiBases, and reference device, TruBase (K213961, K241485)				
Item of Comparison	**Proposed Device TiBases**	**Predicate Device TiBases (K193408)**	**Reference Devices TruBase (K213961, K241485)**	**Similarities and Differences**
	• Osstem/Hiossen Osstem TS, Hiossen ET • Straumann Bone Level, Tissue Level • Thommen Medical Element, Contact • Zimmer External Hex, Certain, Tapered Screw-Vent	• Osstem/Hiossen Osstem TS, Hiossen ET • Straumann Bone Level, Tissue Level • Thommen Medical Element, Contact • Zimmer External Hex, Certain, Tapered Screw-Vent	• Neoss ProActive® (NP, SP) mm. • Camlog Screw-Line • Conelog Screw-Line • Implant Direct Legacy2	
TiBase Component Angulation	0°	0°	0°	Same
TiBase Component Gingival Heights	1, 2, and 3 mm	1 and 2 mm	0.8, 1.8, 2.8, 3.8 mm	Similar. Within the range of the reference device. Fatigue testing was performed to confirm that additional gingival heights do not raise new questions regarding safety and performance.
TiBase Component Post Height	≥ 4 mm	≥ 4 mm	4 - 7 mm	Same as predicate device
Finished CAD/CAM TiBase System Abutment	0 to 20°	0 to 20°	0 to 15°	Same as predicate device

Table 6: Comparison between the proposed TiBases, predicate device (K193408) TiBases, and reference device, TruBase (K213961, K241485)				
Item of Comparison	**Proposed Device TiBases**	**Predicate Device TiBases (K193408)**	**Reference Devices TruBase (K213961, K241485)**	**Similarities and Differences**
Angulation Range				
Restoration type	Single cement-retained restorations	Single or multiple-unit cement retained restorations	Screw-retained single tooth or cement-retained single tooth and bridge restorations	Within range of the predicate and reference devices. The Indications for Use of the TiBases are in line with the indications of the top-half material reference device, CEREC Cercon 4D (K234018), which is indicated for single cement-retained restorations.
Top-Half materials	CEREC Cercon 4D (K234018)	InCoris Zi meso (K111421)	inCoris Zi (K123664)	The inCoris Zi meso (K111421) is discontinued and is replaced with the CEREC Cercon 4D material (K234018). This material was cleared for use with the predicate device TiBases (K193408) via K234018. Fatigue testing is also included to expand the TiBases compatible with the CEREC Cercon 4D and show that this compatibility does not raise new questions on safety and performance.
Workflow	Design and manufacture of top half of abutment performed by clinician/lab in CAD/CAM software system cleared in K193408 and K200191. The CAD/CAM system incorporates the TiBases which	Design and manufacture of top half of abutment performed by clinician/lab in CAD/CAM software system cleared in K193408 and K200191. The CAD/CAM system incorporates the TiBases which	Zirconia superstructure designed and milled by Tru-Abutment-validated milling center	Same as predicate device. The same CAD/CAM system as the predicate device is followed in the workflow. The same software verification process is followed for adding the TiBases into CAD/CAM systems, K193408 and K200191. The performance section of this submission includes the appropriate software verification.

Table 6: Comparison between the proposed TiBases, predicate device (K193408) TiBases, and reference device, TruBase (K213961, K241485)				
Item of Comparison	**Proposed Device TiBases**	**Predicate Device TiBases (K193408)**	**Reference Devices TruBase (K213961, K241485)**	**Similarities and Differences**
	allows for design of the top half of the abutment.	allows for design of the top half of the abutment.		
Sterility	Provided non-sterile (to be steam sterilized)	Provided non-sterile (to be steam sterilized)	Provided non-sterile (to be steam sterilized)	Same

7. Non-Clinical Tests Summary and Conclusion:

The TiBases systems were subjected to fatigue testing per the following requirements and showed similar results when compared to the reference devices (K213961, K241485).

- ISO 14801:2016, "Dentistry-Implants-Dynamic loading test for endosseous dental implants"
- FDA Class II Special Controls Guidance, "Root-form Endosseous Dental Implants and Endosseous Dental Abutments"

MR testing included by reference met the following requirements and supports the MR Conditional labeling of the TiBases systems:

- 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)

Software system verification confirmed that the maximum and minimum design parameters for the customizable two-piece TiBase system abutment device are adequately locked into each of the compatible CAD/CAM software (K193408, K200191) and specifically into the available device design libraries integrated into the software.

Reprocessing testing included by reference was performed according to the following standards and met acceptance criteria:

- ISO 17665-1:2006/(R)2013, "Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices"
- FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"

Biocompatibility assessment and testing were performed to evaluate the biocompatibility profile of the TiBases systems according to the following requirements and met acceptance criteria:

- ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

8. Clinical Tests Summary and Conclusion:

Not applicable. There are no clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

9. Conclusion Regarding Substantial Equivalence:

The proposed TiBase components are made of the same material as the predicate device TiBase components (K193408), which is Ti 6Al-4V ELI, and share the same general intended use in support of partial or fully edentulous mandibles and maxillae for single cement retained restorations. The indications are also similar. In addition, the proposed TiBase components undergo the same manufacturing and packaging process, and are intended to be end user reprocessed similar to the predicate device TiBase components.

Differences include the new gingival height which is similar to the gingival heights offered by the reference devices, TruBase (K213961, K241485). Fatigue testing was performed to demonstrate that the proposed device performs as well as the reference devices (K213961, K241485). In addition, changes to labeling for MR Conditional and changes in the top half material (CEREC Cercon 4D (K234018)) are supported by MR testing, reprocessing, and biocompatibility testing included by reference. Software verification was performed following the same methods in predicate device, K193408, which confirms that the TiBases systems are selectable within the two software systems (Sirona Dental CAD/CAM System with CEREC Chairside Software (K193408) and Sirona Dental CAD/CAM System with inLab Software (K200191)).

Differences in design between the proposed TiBase system, predicate TiBase system (K193408) and reference TruBase (K213961, K241485) devices do not raise new questions regarding safety or performance. The performance and safety data included in this premarket notification support a conclusion of substantial equivalence.