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

May 7, 2024

Re: K234018
Trade/Device Name: CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: December 19, 2023
Received: April 5, 2024

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 (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.

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)*
K234018

Device Name
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System

Indications for Use *(Describe)*
CEREC Cercon 4D™ Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

The system comprises three parts:
- CEREC Cercon 4D™ Abutment Block
- TiBase
- CAD/CAM system

The CEREC Cercon 4D™ ceramic structure cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.

Implant Systems:
• Dentsply Sirona: PrimeTaper EV, OmniTaper EV, AstraTech OsseoSpeed TX, Frialit / XiVE, AstraTech Implant EV, Ankylos
• BioHorizons: Internal connection
• Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Conical Connection, Brånemark, NobelSpeedy Groovy
• Straumann: Tissue Level, Bone Level
• Thommen Medical: Element, Contact
• Osstem/Hiossen: Osstem TS, USA: Hiossen ET
• Zimmer/Biomet: External hex, Certain, Tapered Screw-Vent
• MIS: C1 Conical Connection, V3 Conical Connection, SEVEN internal hex, M4 internal hex
• Altatec – Camlog

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

Manufacturer: Dentsply Sirona Implant
Implant: Primetaper EV
Platform: S; TiBase AT EV 3.6 GH 1 S; Reference: 6586312; Size: S
Platform: M; TiBase AT EV 4.2 GH 1 L; Reference: 6586320; Size: L
Platform: L; TiBase AT EV 4.8 GH 1 L; Reference: 6586338; Size: L

Manufacturer: Dentsply Sirona Implant
Implant: AstraTech OsseoSpeed TX
Platform 3.5 / 4.0; TiBase AT TX 3.5/4.0 GH 1 L; Reference: 6598093; Size: L
Platform 4.5 / 5.0; TiBase AT TX 4.5/5.0 GH 1 L; Reference: 6598101; Size: L
Platform 3.5 / 4.0; TiBase AT OS 3.5/4.0 GH 1 L; Reference: 6282532; Size: L
Platform 4.5 / 5.0; TiBase AT OS 4.5/5.0 GH 1 L; Reference: 6282540; Size: L

Manufacturer: Dentsply Sirona Implant
Implant: Frialit / XiVE
Platform: 3.4; TiBase FX 3.4 GH 1 S; Reference: 6282433; Size: S

Platform: 3.8; TiBase FX 3.8 GH 1 S; Reference: 6282441; Size: S
Platform: 4.5; TiBase FX 4.5 GH 1 L; Reference: 6282458; Size: L
Platform: 5.5; TiBase FX 5.5 GH 1 L; Reference: 6282466; Size: L

Manufacturer: Dentsply Sirona Implant
Implant: AstraTech Implant EV
Platform: XL; TiBase AT EV 5.4 GH 1 L; Reference: 66586346; Size: L

Manufacturer: Dentsply Sirona Implant
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 GH 1 S; Reference: 6532779; Size: S
Platform: 3.5; TiBase BH 3.5 GH 1 L; Reference: 6532894; Size: L
Platform: 4.5; TiBase BH 4.5 GH 1 L; Reference: 6532951; Size: L
Platform: 5.7; TiBase BH 5.7 GH 1 L; Reference: 6536242; Size: L

Manufacturer: Nobel Biocare
Implant: Replace, Replace Select
Platform: NP; TiBase NB RS 3.5 GH 1 L; Reference: 6282474; Size: L
Platform: RP; TiBase NB RS 4.3 GH 1 L; Reference: 6282482; Size: L
Platform: WP; TiBase NB RS 5.0 GH 1 L; Reference: 6282490; Size: L
Platform: 6.0; TiBase NB RS 6.0 GH 1 L; Reference: 6282508; Size: L

Implant: Nobel Active
Platform: NP; TiBase NB A 4.5 GH 1 L; Reference: 6308188; Size: L

Implant: NobelReplace Conical Connection
Platform: RP; TiBase NB A 5.0 GH 1 L; Reference: 6308253; Size: L

Implant: Brånemark
Platform: NP, TiBase NB B 3.4 GH 1 L; Reference: 6282516; Size: L

Implant: NobelSpeedy Groovy
Platform: RP; TiBase NB B 4.1 GH 1 L; Reference: 6282524; Size: L

Manufacturer: Straumann
Implant: Tissue Level
Platform: RN (4.8 mm); TiBase SSO 4.8 GH 1 L; Reference: 6284249; Size: L
Platform: WN (6.5 mm); TiBase SSO 6.5 GH 1 L; Reference: 6284256; Size: L

Implant: Bone Level
Platform: NC (3.3 mm); TiBase S BL 3.3 GH 1 L; Reference: 6308154; Size: L
Platform: RC (4.1 mm / 4.8 mm); TiBase S BL C 4.1 GH 1 L; Reference: 6308337; Size: L

Manufacturer: Thommen Medical
Implant: Element, Contact
Platform: 3.5; TiBase TM 3.5 GH 1 S; Reference: 6531854; Size: S
Platform: 4; TiBase TM 4 GH 1 S; Reference: 6532829; Size: S

Platform: 4.5; TiBase TM 4.5 GH 1 S; Reference: 6532837; Size: S
Platform: 5; TiBase TM 5 GH 1 S; Reference: 6544360; Size: S
Platform: 6; TiBase TM 6 GH 1 S; Reference: 6544378; Size: S

Manufacturer: Osstem / Hiossen
Implant: Osstem TS (US Hiossen ET)
Platform: Mini; TiBase O TS 3.5 GH 1 L; Reference: 6527035; Size: L
Platform: Regular; TiBase O TS 4.0 GH 1 L; Reference: 6527043; Size: L

Manufacturer: Zimmer / Biomet
Implant: External hex
Platform: 3.4; TiBase B O 3.4 GH 1 L; Reference: 6282557; Size: L
Platform: 4.1; TiBase B O 4.1 GH 1 L; Reference: 6282565; Size: L
Platform: 5.0; TiBase B O 5.0 GH 1 L; Reference: 6282573; Size: L

Implant: Certain
Platform: 3.4; TiBase B C 3.4 GH 1 S; Reference: 6308048; Size: S
Platform: 4.1; TiBase B C 4.1 GH 1 L; Reference: 6308097; Size: L
Platform: 5.0; TiBase B C 5.0 GH 1 L; Reference: 6308121; Size: L

Implant: Tapered Screw-Vent
Platform: 3.5; TiBase Z TSV 3.5 GH 1 L; Reference: 6282581; Size: L
Platform: 4.5; TiBase Z TSV 4.5 GH 1 L; Reference: 6282599; Size: L
Platform: 5.7; TiBase Z TSV 5.7 GH 1 L; Reference: 6282607; Size: L

Manufacturer: M.I.S. Implants
Implant: C1 Conical Connection
Platform: NP; TiBase CN-TB001 C1 NP GH 0.5; Reference: CN-TB001; Size: L
Platform: NP; TiBase CN-B015 C1 NP GH 1.5; Reference: CN-TB015; Size: L

Implant: V3 Conical Connection
Platform: NP; TiBase VN-TB001 V3 NP GH 0.5; Reference: VN-TB001; Size: L
Platform: NP; TiBase VN-TB015 V3 NP GH 1.5; Reference: VN-TB015; Size: L

Implant: V3 Conical Connection / C1 Conical Connection
Platform: SP; TiBase CS-TB001 SP GH 0.5; Reference: CS-TB001; Size: L
Platform: SP; TiBase CS-TB015 SP GH 1.5; Reference: CS-TB015; Size: L
Platform: SP; TiBase CS-TB030 SP GH 3; Reference: CS-TB030; Size: L

Implant: C1 Conical Connection
Platform: WP; TiBase CW-TB001 C1 WP GH 0.5; Reference: CW-TB001; Size: L
Platform: WP; TiBase CW-TB015 C1 WP GH 1.5; Reference: CW-TB015; Size: L
Platform: WP; TiBase CW-TB030 C1 WP GH 3; Reference: CW-TB030; Size: L

Implant: SEVEN internal hex, M4 internal hex
Platform: NP; TiBase MN-TB001 INT HEX NP GH 0.5; Reference: MN-TB001; Size: L
Platform: NP; TiBase MN-TBC15 INT HEX NP GH 1.5; Reference: MN-TBC15; Size: L
Platform: SP; TiBase MD-TB001 INT HEX SP GH 0.5; Reference: MD-TB001; Size: L
Platform: SP; TiBase MD-TBC15 INT HEX SP GH 1.5; Reference: MD-TBC15; Size: L
Platform: SP; TiBase MD-TBC30 INT HEX SP GH 3; Reference: MD-TBC30; Size: L
Platform: WP; TiBase MW-TB001 INT HEX WP GH 0.5; Reference: MW-TB001; Size: L
Platform: WP; TiBase MW-TBC15 INT HEX WP GH 1.5; Reference: MW-TBC15; Size: L
Platform: WP; TiBase MW-TBC30 INT HEX WP GH 3; Reference: MW-TBC30; Size: L

Manufacturer: Straumann
Implant: Tissue Level
Platform: NNC (3.5 mm); TiBase NNC Variobase C 3.5 GH 1; Reference: 220.018; Size: S
Platform: RN (4.8 mm); TiBase RN Varionbase C 3.5 GH 1; Reference: 220.019; Size: L
Platform: WN (6.5 mm); TiBase WN Variobase C GH 1; Reference: 220.020; Size: L

Implant: Bone Level
Platform: NC (3.3 mm); TiBase NC Variobase C 3.3 GH 1; Reference: 220.043; Size: S
Platform: RC (4.1 mm / 4.8 mm); TiBase RC Variobase C 4.1 GH 1; Reference: 220.044; Size: L

Manufacturer: Altatec GmbH-Camlog
Implant: Camlog
Platform: 3.3; CAMLOG Titanium Base CADM/CAM, for Ø 3.3 mm GH 0.4; Reference K2244.3348; Size S
Platform: 3.8; CAMLOG Titanium Base CAD/CAM, for Ø 3.8 mm GH 0.3; Reference: K2244.3848; Size: S
Platform: 4.3; CAMLOG Titanium Base CAD/CAM, for Ø 4.3 mm GH 0.3; Reference: K2244.4348; Size: S
Platform: 5.0; CAMLOG Titanium Base CAD/CAM, for Ø 5.0 mm GH 0.3; Reference K2244.5048; Size: L
Platform: 6.0; CAMLOG Titanium Base CAD/CAM, for Ø 6.0 mm GH 0.3; Reference K2244.6048; 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.

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

510(k) SUMMARY
for
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System
(K234018)

1. Submitter Information:

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

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

Date Prepared: 02 May 2024

2. Device Name:
   - Proprietary Name: CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System
   - Classification Name: Endosseous dental implant abutment
   - CFR Number: 872.3630
   - Device Class: Class II
   - Primary Product Code: NHA
   - Secondary Product Code: PNP

3. Predicate/Reference Devices:

Predicate Device Name	510(k)	Company Name
CEREC Tessera Abutment Block, CEREC Tessera Abutment System	K221402	Dentsply Sirona

Reference Device Name	510(k)	Company Name
Technological characteristics / Performance / Composition / Biocompatibility		
Sirona Dental CAD/CAM System (inCoris ZI meso material)	K111421	Dentsply Sirona
Material Composition / Biocompatibility Only		
Cercon	K162888	Dentsply Sirona
Reverse Engineering Compatibility Testing		
Sirona Dental CAD/CAM System with inLab Software	K200191	Dentsply Sirona
Sirona Dental CAD/CAM System with CEREC Chairside Software	K193408	Dentsply Sirona
Sirona Dental CAD/CAM System	K181520	Dentsply Sirona
Sirona Dental CAD/CAM System	K100152	Dentsply Sirona

Compatible Dental Implants	510(k)	Company Name
PrimeTaper EV	K210610	Dentsply Sirona
OmniTaper EV	K221094	Dentsply Sirona
AstraTech OsseoSpeed TX	K053384	Dentsply Sirona
Frialit/ XiVE	K013867	Dentsply Sirona
AstraTech Implant EV	K120414	Dentsply Sirona
Ankylos	K083805	Dentsply Sirona
Internal Connection	K143022, K071638, K093321, K042429	BioHorizons
Replace, Replace Select	K020646	Nobel Biocare
Nobel Active and NobelReplace Conical Connection	K071370	Nobel Biocare
Branemark and NobelSpeedy Groovy	K022562	Nobel Biocare
Straumann Tissue Level and Bone Level	K151324	Straumann
Element, Contact	K093615, K090154	Thommen Medical
Osstem TS (Hiossen ET)	K121585	Osstem/Hiossen
External Hex, Certain and Tapered Screw-Vent	K061410, K061629, K014235	Zimmer/Biomet
C1 Conical Connection, V3 Conical Connection, SEVEN internal hex and M4 internal hex	K191152	Dentsply Sirona
Camlog	K083496	Altatec GmbH

4. Description of Device:

The CEREC Cercon 4D Abutment Blocks, which are used for fabrication of a ceramic structure, two-piece hybrid abutments (meso-structure and crown) and abutment crowns, that are cemented to a TiBase (titanium base) used with dental implant systems. The CEREC Cercon 4D Abutment Blocks are not provided as the finished, fully assembled dental implant medical devices. The abutment blocks are materials supplied to dental professionals that must be further processed/manufactured using CAD/CAM technology and they are not intended to be reused as in the context of direct patient-applied devices and materials.

CEREC Cercon 4D™ Abutment Block are Yttria-doped zirconia blocks suitable for chairside and lab side use in fabrication of single cement-retained restorations. CEREC Ceron 4D™ Abutment Block are designed with a pre-drilled screw access channel and anti-rotation feature. The design allows for fabrication of a ceramic structure, two-piece hybrid abutments (meso-structure and crown) and abutment crowns, that are cemented to the TiBase (Titanium base) used with dental implant systems. The following patient-specific ranges for CAD/CAM fabrication of the subject abutments are:

- Maximum angulation of 20^0
- Minimal wall thickness of 0.5 mm
- Gingival height ranges from 0.3-2.0 mm
- Minimum abutment post height (i.e. length above the gingival height) of ≥ 4 mm

5. Indications for Use:

CEREC Cercon 4D™ Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.
The system comprises three parts:
- CEREC Cercon 4D™ Abutment Block
- TiBase
- CAD/CAM system

The CEREC Cercon 4D™ ceramic structure cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.

Implant Systems:

- Dentsply Sirona: PrimeTaper EV, OmniTaper EV , AstraTech OsseoSpeed TX , Frialit / XiVE , AstraTech Implant EV , Ankylos
- BioHorizons: Internal connection
- Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Conical Connection, Brånemark, NobelSpeedy Groovy
- Straumann: Tissue Level, Bone Level
- Thommen Medical: Element, Contact
- Osstem/Hiossen: Osstem TS, USA:Hiossen ET
- Zimmer/Biomet: External hex, Certain, Tapered Screw-Vent
- MIS: C1 Conical Connection, V3 Conical Connection, SEVEN internal hex, M4 internal hex
- Altatec – Camlog

CAD/CAM Systems:

- Sirona Dental CAD/CAM System

Compatible TiBase and Implant Systems

Implant System		Titanium Base		
Manufacturer / line	**Platform**	**Name**	**REF**	**Size**
Dentsply Sirona Implants				
Primetaper EV	S	TiBase AT EV 3.6 GH 1 S	6586312	S
	M	TiBase AT EV 4.2 GH 1 L	6586320	L
	L	TiBase AT EV 4.8 GH 1 L	6586338	L
AstraTech OsseoSpeed TX	3.5 / 4.0	TiBase AT TX 3.5/4.0 GH 1 L	6598093	L
	4.5 / 5.0	TiBase AT TX 4.5/5.0 GH 1 L	6598101	L
	3.5 / 4.0	TiBase AT OS 3.5/4.0 GH 1 L	6282532	L
	4.5 / 5.0	TiBase AT OS 4.5/5.0 GH 1 L	6282540	L
Frialit / Xive	3.4	TiBase FX 3.4 GH 1 S	6282433	S
	3.8	TiBase FX 3.8 GH 1 S	6282441	S
	4.5	TiBase FX 4.5 GH 1 L	6282458	L
	5.5	TiBase FX 5.5 GH 1 L	6282466	L
AstraTech Implant EV	XL	TiBase AT EV 5.4 GH 1 L	6586346	L
Ankylos	C/X	TiBase ANK C/ GH 1 S	6586528	S
		TiBase ANK C/ GH 2 S	6586536	S
		TiBase ANK /X GH 1 S	6586544	S
		TiBase ANK /X GH 2 S	6586551	S
BioHorizons				
Internal connection	3.0	TiBase BH 3.0 GH 1 S	6532779	S
	3.5	TiBase BH 3.5 GH 1 L	6532894	L
	4.5	TiBase BH 4.5 GH 1 L	6532951	L
	5.7	TiBase BH 5.7 GH 1 L	6536242	L
Nobel Biocare				
Replace, Replace Select	NP	TiBase NB RS 3.5 GH 1 L	6282474	L
	RP	TiBase NB RS 4.3 GH 1 L	6282482	L
	WP	TiBase NB RS 5.0 GH 1 L	6282490	L
	6.0	TiBase NB RS 6.0 GH 1 L	6282508	L
Nobel Active	NP	TiBase NB A 4.5 GH 1 L	6308188	L
NobelReplace Conical Connection	RP	TiBase NB A 5.0 GH 1 L	6308253	L
Brånemark	NP	TiBase NB B 3.4 GH 1 L	6282516	L
NobelSpeedy Groovy	RP	TiBase NB B 4.1 GH 1 L	6282524	L
Straumann				
Tissue Level	RN (4.8 mm)	TiBase SSO 4.8 GH 1 L	6284249	L
	WN (6.5 mm)	TiBase SSO 6.5 GH 1 L	6284256	L
Bone Level	NC (3.3 mm)	TiBase S BL 3.3 GH 1 L	6308154	L
	RC (4.1 mm / 4.8 mm)	TiBase S BL 4.1 GH 1 L	6308337	L
Thommen Medical				
Element, Contact	3.5	TiBase TM 3.5 GH 1 S	6531854	S
	4	TiBase TM 4 GH 1 S	6532829	S
	4.5	TiBase TM 4.5 GH 1 S	6532837	S
	5	TiBase TM 5 GH 1 S	6544360	S
	6	TiBase TM 6 GH 1 S	6544378	S

Implant System		Titanium Base		
Manufacturer / line	**Platform**	**Name**	**REF**	**Size**
Osstem / Hiossen				
Osstem TS	Mini	TiBase O TS 3.5 GH 1 L	6527035	L
(USA: Hiossen ET)	Regular	TiBase O TS 4.0 GH 1 L	6527043	L
Zimmer /Biomet				
External hex	3.4	TiBase B O 3.4 GH 1 L	6282557	L
	4.1	TiBase B O 4.1 GH 1 L	6282565	L
	5.0	TiBase B O 5.0 GH 1 L	6282573	L
Certain	3.4	TiBase B C 3.4 GH 1 S	6308048	S
	4.1	TiBase B C 4.1 GH 1 L	6308097	L
	5.0	TiBase B C 5.0 GH 1 L	6308121	L
Tapered Screw-Vent	3.5	TiBase Z TSV 3.5 GH 1 L	6282581	L
	4.5	TiBase Z TSV 4.5 GH 1 L	6282599	L
	5.7	TiBase Z TSV 5.7 GH 1 L	6282607	L
M.I.S				
C1 Conical Connection	NP	CN-TB001 C1 NP GH 0.5	CN-TB001	L
		CN-TB015 C1 NP GH 1.5	CN-TB015	L
V3 Conical Connection	NP	VN-TB001 V3 NP GH 0.5	VN-TB001	L
		VN-TB015 V3 NP GH 1.5	VN-TB015	L
V3 Conical Connection, C1 Conical Connection	SP	CS-TB001 SP GH 0.5	CS-TB001	L
		CS-TB015 SP GH 1.5	CS-TB015	L
		CS-TB030 SP GH 3	CS-TB030	L
C1 Conical Connection	WP	CW-TB001 C1 WP GH 0.5	CW-TB001	L
		CW-TB015 C1 WP GH 1.5	CW-TB015	L
		CW-TB030 C1 WP GH 3	CW-TB030	L
SEVEN internal hex, M4 internal hex	NP	MN-TB001 INT HEX NP GH 0.5	MN-TB001	L
		MN-TBC15 INT HEX NP GH 1.5	MN-TBC15	L
	SP	MD-TB001 INT HEX SP GH 0.5	MD-TB001	L
		MD-TBC15 INT HEX SP GH 1.5	MD-TBC15	L
		MD-TBC30 INT HEX SP GH 3	MD-TBC30	L
	WP	MW-TB001 INT HEX WP GH 0.5	MW-TB001	L
		MW-TBC15 INT HEX WP GH 1.5	MW-TBC15	L
		MW-TBC30 INT HEX WP GH 3	MW-TBC30	L
Straumann				
Tissue Level	NNC (3.5 mm)	NNC Variobase C 3.5 GH 1	220.018	S
	RN (4.8 mm)	RN Variobase C GH 1	220.019	L
	WN (6.5 mm)	WN Variobase C GH 1	220.020	L
Bone Level	NC (3.3 mm)	NC Variobase C 3.3 GH 1	220.043	S
	RC (4.1 mm / 4.8 mm)	RC Variobase C 4.1 GH 1	220.044	L
Camlog				
Camlog	3.3	CAMLOG® Titanium base CAD/CAM, for Ø 3.3 mm GH 0.4	K2244.3348	S
	3.8	CAMLOG® Titanium base CAD/CAM ,for Ø 3.8 mm GH 0.3	K2244.3848	S
	4.3	CAMLOG® Titanium base CAD/CAM, for Ø 4.3 mm GH 0.3	K2244.4348	S
	5.0	CAMLOG® Titanium base CAD/CAM, for Ø 5.0 mm GH 0.3	K2244.5048	L
	6.0	CAMLOG® Titanium base CAD/CAM, for Ø 6.0 mm GH 0.3	K2244.6048	L

6. Substantial Equivalence:
The indications for use of the proposed device do not constitute a new intended use. The proposed CEREC Cercon 4D™ Abutment Block has the same intended use and similar indications for use compared to the predicate, CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402) and reference device Sirona Dental CAD/CAM System (inCoris ZI meso material) (K111421) in that they are used with TiBases, Implant Systems and CAD/CAM technology. The main difference is the compatible Implant systems and titanium bases. The block material and TiBase make up an abutment crown or a 2-piece hybrid abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. Table 6.1 and Table 6.2 compare the Intended Use and Indications for Use when compared to the predicate and reference devices.

Table 6.1-Comparison of Intended Use			
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)	**Predicate Device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Reference Device Sirona Dental CAD/CAM System** (inCoris ZI meso material) **(K111421)**	**Discussion**
CEREC Cercon 4D™ Abutment Blocks are a ceramic intended for fixed dental prosthetic restorations.	CEREC Tessera Abutment Blocks are a ceramic intended for fixed dental prosthetic restorations.	inCoris ZI meso blocks are intended for use in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.	The proposed and predicate device have the same Intended Use. The Intended Use of the reference device is similar to Intended Use of the proposed and predicate devices in that the mesostructure is cemented to the titanium base as part of a two-piece hybrid abutment.

Table 6.2 - Comparison of Indications for Use			
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)	**Predicate Device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Reference Device Sirona Dental CAD/CAM System (inCoris ZI meso material) (K111421)**	**Discussion**
CEREC Cercon 4D™ Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts: • CEREC Cercon 4D™ Abutment Block • TiBases • CAD/CAM system	CEREC Tessera Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts: - CEREC Tessera Abutment Block - TiBase - CAD/CAM system	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software.	Same as predicate and reference devices. The reference device is additionally indicated for multiple-unit cement retained restorations which pertains to other materials used within the CAD/CAM system.
The CEREC Cercon 4D™ ceramic structure cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.	The CEREC Tessera ceramic structure cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.	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 proposed and predicate devices are the same. The reference device is similar with an additional use with Camlog Implant System and Titanium base. The proposed block is also indicated for use with the Camlog (3rd party products). Fatigue testing to support the use with 3rd party implant systems and TiBases is included in the Performance Bench Testing section.

Table 6.2 - Comparison of Indications for Use			
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)	**Predicate Device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Reference Device Sirona Dental CAD/CAM System (inCoris ZI meso material) (K111421)**	**Discussion**
Implant Systems: • Dentsply Sirona: PrimeTaper EV, OmniTaper EV, AstraTech OsseoSpeed TX, Frialit / XiVE, AstraTech Implant EV, Ankylos • BioHorizons: Internal connection • Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Conical Connection , Brånemark, NobelSpeedy Groovy • Straumann: Tissue Level, Bone Level • Thommen Medical: Element, Contact • Osstem/Hiossen: Osstem TS , USA:Hiossen ET • Zimmer/Biomet: External hex, Certain, Tapered Screw-Vent • MIS: C1 Conical Connection, V3 Conical Connection, SEVEN	The compatible Implant systems, titanium bases and CAD/CAM systems are shown below: Implant Systems: • Dentsply Sirona: AstraTech OsseoSpeed TX (K053384), XiVE (K013867), AstraTech Implant EV (K120414), Ankylos (K083805), PrimeTaper EV (K210610) • MIS: C1 Conical connection (K172505 NP, K180282 WP), V3 Conical connection (K163349), SEVEN internal hex (K112162), M4 internal hex (K112162) CAD/CAM Systems: • Sirona Dental CAD/CAM System (K193408, K200191) Titanium Bases: • Refer to Table 6.2a for the compatible Titanium Bases	The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: • Nobel Biocare Replace (K020646) • Nobel Biocare Branemark (K022562) • Friadent Xive (K001386) • Biomet 3i Osseotite (K980549) • Astra Tech Osseospeed (K091239) • Zimmer Tapered Screw-Vent (K061410) • Straumann SynOcta (K061176) • Straumann Bone Level (K053088) • Biomet 3i Certain (K014235) • Nobel Biocare Active (K071370)	Proposed device does not include implant system or titanium bases in the Indications for Use statement. Instead, a compatibility table for the Implant Systems and TiBases is included within the Instructions for Use (IFU).

Table 6.2 - Comparison of Indications for Use			
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)	**Predicate Device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Reference Device Sirona Dental CAD/CAM System (inCoris ZI meso material) (K111421)**	**Discussion**
internal hex, M4 internal hex • Altatec – Camlog CAD/CAM Systems: • Sirona Dental CAD/CAM System Refer to compatible Titanium Bases and Implant Systems Table above in the Indications for Use-Section 5.			

Table 6.2a- Compatibility Table included in the Predicate Device Indications for Use Statement above				
Implant system		**Titanium base**		
Manufacturer / line	**Platform**	**Name**	**REF**	**Size**
Dentsply Sirona Implants				
AstraTech OsseoSpeed TX (K053384)	3.5 / 4.0	TiBase AT OS 3.5/4.0 L	6282532	L
	4.5 / 5.0	TiBase AT OS 4.5/5.0 L	6282540	L
	3.5 / 4.0	TiBase AT TX 3.5/4.0 L	6598093	L
	4.5 / 5.0	TiBase AT TX 4.5/5.0 L	6598101	L
XiVE (K013867)	3.4	TiBase FX 3.4 S	6282433	S
	3.8	TiBase FX 3.8 S	6282441	S
	4.5	TiBase FX 4.5 L	6282458	L
	5.5	TiBase FX 5.5 L	6282466	L
AstraTech Implant EV (K120414) Prime Taper EV (K210610)	S	TiBase AT EV 3.6 GH1 S	6586312	S
	M	TiBase AT EV 4.2 GH1 L	6586320	L
	L	TiBase AT EV 4.8 GH1 L	6586338	L
AstraTech Implant EV (K120414)	XL	TiBase AT EV 5.4 GH1 L	6586346	L
Ankylos (K083805)	C/X	TiBase ANK C/ GH1 S	6586528	S
		TiBase ANK C/ GH2 S	6586536	S
		TiBase ANK /X GH1 S	6586544	S
		TiBase ANK /X GH2 S	6586551	S
M.I.S. Implants				
C1 Conical Connection (K172505)	NP	CN-TB001 C1 NP GH 0.5	CN-TB001	L
		CN-TB015 C1 NP GH 1.5	CN-TB015	L
V3 Conical Connection (K163349)	NP	VN-TB001 V3 NP GH 0.5	VN-TB001	L
		VN-TB015 V3 NP GH 1.5	VN-TB015	L
SEVEN internal hex, M4 internal hex (K112162)	NP	MN-TB001 INT HEX NP GH 0.5	MN-TB001	L
		MN-TBC15 INT HEX NP GH 1.5	MN-TBC15	L
	SP	MD-TB001 INT HEX SP GH 0.5	MD-TB001	L
		MD-TBC15 INT HEX SP GH 1.5	MD-TBC15	L
		MD-TBC30 INT HEX SP GH 3	MD-TBC30	L
	WP	MW-TB001 INT HEX WP GH 0.5	MW-TB001	L
		MW-TBC15 INT HEX WP GH 1.5	MW-TBC15	L
		MW-TBC30 INT HEX WP GH 3	MW-TBC30	L

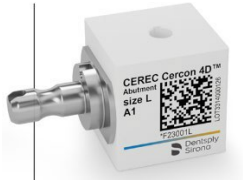
7. Technological Comparison:

The proposed CEREC Cercon 4D™ Abutment Block is similar in intended use, design, principles of operation and meet the requirements of ISO 14801:2016 compared to the predicate device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402) and the reference device Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421). The only difference between the proposed, predicate and reference devices is the material. The proposed and reference devices are zirconia material, whereas the predicate is an advanced lithium disilicate material. Table 7.1 compares the technological characteristics of the proposed device compared to the predicate and reference devices.

Table 7.1: Comparison between the proposed CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System, the predicate device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402) and reference device inCoris ZI meso (K111421)

Item of Comparison	Proposed Device CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)	Predicate Device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)	Reference Device Sirona Dental CAD/CAM System (inCoris ZI meso material) (K111421)	Similarities and Differences
Product Code	Primary: NHA Secondary: PNP	Primary: NHA Secondary: PNP	NHA	Same to the predicate device and similar to the reference device
Manufacturer	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Same
Abutment Angle	0° to 20°	0° to 20°	0° to 20°	Same
Restoration	Single Unit	Single Unit	Single Unit	Same
Material	Zirconia[1]	Advanced Lithium Disilicate	Zirconia[1]	The proposed and reference device are both zirconia materials. The predicate device differs in material.
Cement (Adhesive/Glue)	Calibra Abutment Resin Cement	Calibra Cement	No specific cement referenced	Similar, the role of the cement is to glue the crown or meso-structure to the TiBase
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same

[1] Yttrium Oxide is present in the proposed device CEREC Cercon 4D™ Abutment Blocks as well as the reference devices inCoris ZI meso material (K111421) and Cercon® (K162888). Component concentrations in the proposed device formulation are similar to those of the reference devices' formulations and support biocompatibility (refer to the Biocompatibility section).

Table 7.1: Comparison between the proposed CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System, the predicate device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402) and reference device inCoris ZI meso (K111421)				
Item of Comparison	**Proposed Device CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)**	**Predicate Device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Reference Device Sirona Dental CAD/CAM System (inCoris ZI meso material) (K111421)**	**Similarities and Differences**
Sterilization Method	Steam Sterilization (final, assembled prosthetic restoration)	Steam Sterilization (final, assembled prosthetic restoration)	Steam sterilization (final, assembled prosthetic restoration)	Same
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Same
Fatigue	Meets ISO 14801 requirements	Meets ISO 14801 requirements	Meets ISO 14801 requirements	Same
Flexural Strength	Meets ISO 6872:2015 (Amd 1. 2018) requirements	Meets ISO 6872:2015 (Amd 1. 2018) requirements	Meets ISO 6872:2015 (Amd 1. 2018) requirements	Same
Software Verification	Meets internal software integration requirements for the addition of the proposed device CEREC Cercon 4D Abutment Blocks	Meets internal software integration requirements for the addition of the CEREC Tessera Abutment Block	Meets internal software integration requirements for the addition of the inCoris ZI meso	Same. The proposed, predicate and reference devices have all been integrated into the compatible Sirona CAD/CAM System software (K193408, K200191).
Design				Same. The proposed, predicate and reference devices are all shaped like a block and have a screw access channel.
MRI Safety Labeling	MRI Conditional	MRI Conditional	---	Same as predicate

8. Non-Clinical Tests Summary and Conclusion:

Performance Testing:

The proposed device was tested and conforms to ISO 6872:2015 (Amd 1. 2018) Dentistry-Ceramic Materials and ISO 14801:2016 Dentistry-Implants-Dynamic loading test for endosseous dental implants. Additionally, software system verification was performed as part of the non-clinical testing. Table 8.1 summarizes the performance bench testing for flexural strength conducted on the proposed device according to ISO 6872:2015 (Amd 1. 2018). Table 8.2 summarizes the performance bench testing for fatigue strength according to ISO 14801:2016. New fatigue testing was conducted on the worst-case combinations relating to the greatest angulation, the platform size and the gingival height for the proposed Dentsply Sirona TiBase/Dentsply Sirona Implant Systems and Third Party TiBase/Third Party Implant Systems (Camlog) combinations. The testing conducted together with historical data on file for the reference device (K111421) was leveraged to support performance of Dentsply Sirona TiBase/Third Party Implant Systems, and Dentsply Sirona TiBase/Dentsply Sirona Implant Systems, and Third Party TiBase/Third Party Implant Systems combinations.

Table 8.1- Performance Specifications-Flexural Strength

Test Performed	Test method/Applicable Standards	Acceptance Criteria	Results
Flexural Strength (3-point bending strength)	ISO 6872:2015 Amd 1. 2018 *Dentistry-Ceramic Materials*	>1,100 MPa	Pass

Table 8.2- Performance Specifications-Fatigue Strength

Test Performed	Test method/Applicable Standards	Results
Fatigue Testing after steam sterilization- MIS Narrow Platform conical connection C1-10330 with CN-TB015 TiBase	ISO 14801:2016 *Dentistry-Implants-Dynamic loading test for endosseous dental implants*	Pass
Fatigue Testing after steam sterilization- MIS Standard Platform conical connection C1-08375 with CS-TB030 TiBase		Pass
Fatigue Testing after steam sterilization- DS XiVE S Plus implant D3.4/L15 with DS TiBase FX 3.4 S		Pass
Fatigue Testing after steam sterilization- Camlog Screw-Line Implant nominal size 3.8mm length 13.mm with Camlog Titanium Base CAD/CAM		Pass

Cleaning, Disinfection, and Sterilization Testing:
Sterilization validation testing was conducted in accordance with ISO 17665-1 *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.* The validation process was validated using a hybrid method to ensure that the proposed device can be steam sterilized and achieve a Sterility Assurance Level (SAL) of 10^{-6} in support of the following dynamic air removal (pre-vacuum) steam sterilization parameters:

- 132°C (270°F) for 4 minutes; Dry Time=20 minutes
- 135°C (275°F) for 3 minutes; Dry Time=16 minutes

CAD/CAM Software Validation & Verification Testing:
Software validation was performed to show the maximum and minimum design parameters for the CEREC Cercon 4D™ Abutment Block, CEREC Cercon 4D™ Abutment System within the compatible CAD/CAM software. The following parameters are locked into the CAD/CAM software libraries:

- Maximum angulation of 20˚
- Minimal wall thickness of 0.5 mm

The angulation within the CAD/CAM system is fixed and set across all libraries. If the user choses an angulation outside the set value, they will get an error screen that is red in color that indicates a "stop" and the user will not be able to proceed without updating the design to meet the angulation set within the system.

The wall thickness parameter is defined in the CAD/CAM library for the material itself. Ifthe user choses a wall thickness outside the defined parameter, they will get an error screen and will not be able to proceed without updating the design to meet the wall thickness parameter.

Adding implant/abutment compatibilities to the CAD/CAM library is restricted by the implant/abutment manufacturer's assigned parameters. The gingival height (GH) is defined by the TiBase chosen and there is no option within the CAD/CAM system to change the GH. The TiBase chosen also defines the post height (PH) which is a restricted value set by the manufacturer of the TiBase. Once the TiBase is chosen for that material the GH and PH are defined and cannot be altered by the user during the design phase. When a new implant/TiBase is added to the CAD/CAM library, the manufacturer provides Dentsply Sirona with those parameters and a separate verification is conducted. Third-party compatibilities are added through the device master file system.

Biocompatibility Testing:
A biological risk assessment was conducted on the proposed device, CEREC Cercon 4D™ Abutment Block, CEREC Cercon 4D™ Abutment System. Review of available information on raw materials, manufacturing processes, chemical characterization tests and existing preclinical biological testing data concludes that the test results meet the requirements of the following ISO 10993 standard series.

The following tests were conducted:

- Cytotoxicity (ISO 10993-5:2009 *Biological Evaluation of Medical Devices-Part 5 Test for In Vitro Cytotoxicity*)
- Sensitization (ISO 10993-10:2021 *Biological Evaluation of Medical Devices-Part 10 Test for Skin Sensitization*)
- Irritation (ISO 10993-23:2021 *Biological Evaluation of Medical Devices-Part 23 Test for Irritation*)

Conclusion:
Minor differences in the technological characteristics between the proposed and predicate (K221402) devices were evaluated through appropriate fatigue testing, performance bench testing, software validation and verification, and biocompatibility testing, which demonstrated that the proposed device, when compared to the predicate device, does not raise new questions regarding safety and effectiveness. Therefore, the nonclinical testing data supports the conclusion that the proposed device performs as well as the predicate device (K221402).

9. Clinical Tests Summary and Conclusion:
   Not applicable. No data from human clinical studies has been included to support the substantial equivalence of CEREC Cercon 4D™ Abutment Block, CEREC Cercon 4D™ Abutment System.

10. Conclusion Regarding Substantial Equivalence:
    The proposed CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System has the same Intended Use and nearly identical Indications for Use as compared to the predicate device, CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402) and the reference device, Sirona Dental CAD/CAM System (inCoris ZI meso material (K111421)). The proposed, predicate and reference devices also share the same fundamental technology. The reference devices, Sirona Dental CAD/CAM System (inCoris ZI meso material (K111421)) and Cercon (K162888) are similar in material composition when compared to the proposed device. Test data is included in this premarket notification to verify the safety and performance requirements of the proposed device and the results support a conclusion of substantial equivalence.