November 26, 2025

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

Re: K252248
Trade/Device Name: CEREC Tessera Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: July 17, 2025
Received: October 28, 2025

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.

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252248 ?

Please provide the device trade name(s). ?

CEREC Tessera Abutment System

Please provide your Indications for Use below. ?

CEREC Tessera Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

For BH 3.0 S, NC Variobase C 3.3, Camlog 3.3 S and S BL 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:
- CEREC Tessera Abutment Block
- TiBase
- CAD/CAM system

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.
The compatible Implant systems, titanium bases and CAD/CAM systems are shown below:
Implant Systems:
- Dentsply Sirona: AstraTech OsseoSpeed TX, Ankylos
- BioHorizons: Internal connection
- Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Concial 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
- MIS: C1 Conical connection (NP and WP), V3 Conical connection , SEVEN internal hex, M4 internal hex

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

Titanium Bases:

Implant: AstraTech Osseospeed TX
Platform: 3.5/4.0; TiBase AT TX 3.5/4.0 GH1 L; Reference 6598093; Size L
Platform: 4.5/5.0; TiBase AT TX 4.5/5.0 GH1 L; Reference 6598101; Size L
Platform: 3.5/4.0; TiBase AT OS 3.5/4.0 GH1 L; Reference 6282532; Size L
Platform: 4.5/5.0; TiBase ATOS 4.5/5.0 GH1 L; Reference 6282540; Size L

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

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

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

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

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

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, Nobel Replace Conical Connection
Platform: NP; TiBase NB A 4.5 GH 1 L; Reference 6308188; Size: L
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: Straumann
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 CAD/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		
Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

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

SECTION 5. 510(k) SUMMARY
for
CEREC Tessera Abutment System (K252248)

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17404

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

Date Prepared: November 25, 2025

2. Device Name:
   - Proprietary Name: CEREC Tessera Abutment System
   - Classification Name: Endosseous dental implant abutment
   - CFR Number: 21 CFR 872.3630
   - Device Class: II
   - Primary Product Code: NHA - Abutment, Implant, Dental Endosseous,
   - Secondary Product Code: PNP - Dental Abutment Design Software for Dental Laboratory

3. Predicate and Reference Devices:
   The predicate and reference devices are noted below:

Predicate Device:

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

Reference Devices in support for fatigue testing:

Reference Device Name	510(k)	Company Name
CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System	K234018	Dentsply Sirona
Dentsply Sirona Titanium Bases system	K250295	Dentsply Sirona
Sirona Dental CAD/CAM System (inCoris ZI meso)	K111421	Dentsply Sirona

Reference Devices of compatible implant systems:

Reference Device Name	510(k)	Company Name
Compatible Dental Implants		
Internal Connection	K143022, K071638, K093321, K042429	BioHorizons
Replace, Replace Select	K020646	Nobel Biocare
Nobel Active / NobelReplace Conical Connection	K071370	Nobel Biocare
Branemark and NobelSpeedy Groovy	K022562	Nobel Biocare
Tissue Level and Bone Level	K151324	Straumann
Bone Level	K192742	Straumann
Element, Contact	K093615, K090154	Thommen Medical
Ossten TS (USA : Hiossen ET)	K121585	Osstem/Hiossen
External Hex, Certain and Tapered Screw-Vent	K061410, K061629, K014235	Zimmer/Biomet
Camlog	K083496	Altatec GmbH
MIS Ti-base Abutment (C1 Conical Connection, V3 Conical Connection, SEVEN internal hex and M4 internal hex)	K191152	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

4. Description of Device:

The proposed CEREC Tessera Abutment System is a modification of the previously cleared CEREC Tessera Abutment Block (K221402). The proposed CEREC Tessera Abutment Blocks are intended for fabrication of single cement-retained restorations. The proposed CEREC Tessera Abutment System (with the additional TiBase and Implant System compatibilities and change in wall thickness) is comprised of the CEREC Tessera Abutment Block , applicable TiBase, and CAD/CAM systems in both chairside (CEREC chairside software) and labside (inLab labside software) use. The CEREC Tessera Abutment Blocks are not provided as the finished, fully assembled dental implant medical device. The CEREC Tessera 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.

The CEREC Tessera Abutment Blocks are designed with a pre-drilled screw access channel and anti-rotation feature. The design allows for fabrication of a ceramic structure used to create 2-piece hybrid abutments and hybrid abutment crowns cemented to a TiBase used with dental implant systems. The patient-specific ceramic structure is then cemented to a TiBase to create the two-piece abutment which constitutes the final finished medical device. The following patient-specific ranges for CAD/CAM fabrication of the abutments are:

- Maximum angulation of 20°
- Minimal wall thickness of 0.5 mm
- Gingival height ranges from 0.5 mm -3.0 mm
- Minimum abutment post height (i.e. length above the gingival height) of ≥4 mm

5. Indications for Use:

CEREC Tessera Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

For BH 3.0 S, NC Variobase C 3.3, Camlog 3.3 S and S BL 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:

- *CEREC Tessera Abutment Block*
- *TiBase*
- *CAD/CAM system*

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.

The compatible Implant systems, titanium bases and CAD/CAM systems are shown below:
Implant Systems:

- *Dentsply Sirona: AstraTech OsseoSpeed TX, Ankylos*
- *BioHorizons: Internal connection*
- *Nobel Biocare: Replace, Replace Select, Nobel Active, NobelReplace Concial 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*
- *MIS: C1 Conical connection (NP and WP), V3 Conical connection , SEVEN internal hex , M4 internal hex*

CAD/CAM Systems:

- *Sirona Dental CAD/CAM System*

Titanium Bases:

Implant System		Titanium Base		
Manufacturer/Line	**Platform**	**Name**	**REF**	**Size**
Dentsply Sirona Implants				
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
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
M.I.S Implants				
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
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				
	NP	TiBase NB RS 3.5 GH 1 L	6282474	L
	RP	TiBase NB RS 4.3 GH 1 L	6282482	L

Implant System		Titanium Base		
Manufacturer/Line	**Platform**	**Name**	**REF**	**Size**
Replace, Replace Select	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 NobelReplace Conical Connection	NP	TiBase NB A 4.5 GH 1 L	6308188	L
	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
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
Straumann				
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:

   For the purpose of substantial equivalence, the proposed CEREC Tessera Abutment System is compared to the legally marketed predicate device CEREC Tessera Abutment Blocks, CEREC Tessera Abutment System (K221402). The proposed CEREC Tessera Abutment System is also compared to the reference devices, CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018), Dentsply Sirona Titanium Bases system (K250295), and Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421), to support the fatigue limits (performance bench testing). The proposed, predicate and reference devices share similar indications for use, and technological characteristics. Table 6.1 and Table 6.2 includes a comparison of the proposed, predicate and reference devices Indications for Use.

The proposed CEREC Tessera Abutment System is compatible with additional TiBase and implants system compatibilities when compared to the predicate device. Table 6.1 compares the proposed compatible implant systems with those for the predicate device. The proposed compatible implant systems are based on the marketing strategy for the proposed CEREC Tessera Abutment Block.

Table 6.1 – Comparison of Indications for Use- Proposed and Predicate device systems		
Proposed **CEREC Tessera Abutment System**	**Predicate Device** **CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Discussion**
CEREC Tessera Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. For BH 3.0 S, NC Variobase C 3.3, Camlog 3.3 S and S BL 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: • CEREC Tessera Abutment Block • TiBase • 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	Similar with the exception of the limited Indications for Use of certain compatible TiBases that are being added as compatible with this proposed premarket notification. The restricted indications for the compatible TiBases is in alignment with the indications that are included in their separate clearance from the FDA.
The CEREC Tessera Abutment 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 Abutment 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.	Same
The compatible Implant systems, titanium bases and CAD/CAM systems are shown below: Implant Systems including DS TiBase: • Dentsply Sirona: AstraTech OsseoSpeed TX; Ankylos • MIS: C1 Conical connection ; V3 Conical connection; SEVEN internal hex, M4 internal hex • BioHorizons: Internal Connection • Zimmer/Biomet: External Hex; Certain; Tapered Screw Vent	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)	The proposed device has additional 3rd party TiBase with 3rd party Implant combinations. The proposed device also has additional Dentsply Sirona Implant Systems with Dentsply Sirona TiBases and 3rd Party Implant Systems with Dentsply Sirona TiBase combinations. XiVE is being removed due to

Table 6.1 – Comparison of Indications for Use- Proposed and Predicate device systems		
Proposed **CEREC Tessera Abutment System**	**Predicate Device** **CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)**	**Discussion**
• Nobel Biocare: Replace, Replace Select; Nobel Active, NobelReplace Conical Connection; Branemark; NobelSpeedy, Groovy • Straumann: Tiisue Level; Bone Level • Thommen Medical: Element, Contact • Osstem/Hoisen: Osstem TS (USA: Hiosen ET) • Camlog: Camlog		discontinuation. Performance data to support the additional compatibilities is included in the Performance Bench Testing section.
CAD/CAM Systems: • Sirona Dental CAD/CAM System	CAD/CAM Systems: • Sirona Dental CAD/CAM System (K193408, K200191)	Same
Refer to Table 6.1a below for the compatibilities tables that will be part of the indications for use.	Refer to Table 6.1a below for the compatibilities tables that will be part of the indications for use.	Proposed device has additional 3rd party TiBase and Implant combinations. Refer to Table 6.1a below for the compatibilities tables that will be part of the indications for use.

Table 6.1a- TiBase and Implant Compatibility Table as part of the Indications for Use										
Proposed CEREC Tessera Abutment System						**Predicate CEREC Tessera Abutment Blocks, CEREC Tessera Abutment System (K221402)**				
Implant system		**Titanium base**				**Implant system**		**Titanium base**		
Manufacturer /line	**Platform**	**Name**	**REF**	**Size**		**Manufacturer/ line**	**Platform**	**Name**	**REF**	**Size**
Dentsply Sirona Implants						**Dentsply Sirona Implants**				
AstraTech OsseoSpeed TX	3.5 / 4.0	TiBase AT OS 3.5/4.0 GH 1 L	6282532	L		AstraTech OsseoSpeed TX	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 GH 1 L	6282540	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 GH 1 L	6598093	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 GH 1 L	6598101	L			4.5 / 5.0	TiBase AT TX 4.5/5.0 L	6598101	L
Ankylos	C/X	TiBase ANK C/ GH1 S	6586528	S		XiVE	3.4	TiBase FX 3.4 S	6282433	S
		TiBase ANK C/ GH2 S	6586536	S			3.8	TiBase FX 3.8 S	6282441	S
		TiBase ANK /X GH1 S	6586544	S			4.5	TiBase FX 4.5 L	6282458	L
		TiBase ANK /X GH 2 S	6586551	S			5.5	TiBase FX 5.5 L	6282466	L
M.I.S. Implants						AstraTech Implant EV PrimeTaper EV	S	TiBase AT EV 3.6 GH1 S	6586312	S
C1 Conical Connection	NP	CN-TB001 C1 NP GH 0.5	CN-TB001	L			M	TiBase AT EV 4.2 GH1 L	6596320	L
		CN-TB015 C1 NP GH 1.5	CN-TB015	L			L	TiBase AT EV 4.8 GH1 L	6586388	L
V3 Conical Connection	NP	VN-TB001 V3 NP GH 0.5	VN-TB001	L			XL	TiBase AT EV 5.4 GH1 L	6586346	L
		VN-TB015 V3 NP GH 1.5	VN-TB015	L		AstraTech Implant EV				
V3 Conical Connection, C1 Conical Connection	SP	CS-TB001 SP GH 0.5	CS-TB001	L		Ankylos	CX	TiBase ANK C/ GH1 S	6586528	S
		CS-TB015 SP GH 1.5	CS-TB015	L				TiBase ANK C/ GH2 S	6586536	S
		CS-TB030 SP GH 3	CS-TB030	L				TiBase ANK /X GH1 S	6586544	S
C1 Conical Connection	WP	CW-TB001 C1 WP GH 0.5	CW-TB001	L				TiBase ANK /X GH2 S	6586551	S
		CW-TB015 C1 WP GH 1.5	CW-TB015	L		**M.I.S. Implants**				
		CW-TB030 C1 WP GH 3	CW-TB030	L		C1 Conical Connection	NP	CN-TB001 C1 NP GH 0.5	CN-TB001	L
SEVEN internal hex, M4 internal hex	NP	MN-TB001 INT HEX NP GH 0.5	MN-TB001	L				CN-TB015 C1 NP GH 1.5	CN-TB015	L
		MN-TBC15 INT HEX NP GH 1.5	MN-TBC15	L		V3 Conical Connection	NP	VN-TB001 V3 NP GH 0.5	VN-TB001	L
	SP	MD-TB001 INT HEX SP GH 0.5	MD-TB001	L				VN-TB015 V3 NP GH 1.5	VN-TB015	L
		MD-TBC15 INT HEX SP GH 1.5	MD-TBC15	L		V3 Conical Connection, C1 Conical Connection	SP	CS-TB001 SP GH 0.5	CS-TB001	L
		MD-TBC30 INT HEX SP GH 3	MD-TBC30	L				CS-TB015 SP GH 1.5	CS-TB015	L
	WP	MW-TB001 INT HEX WP GH 0.5	MW-TB001	L				CS-TB030 SP GH 3	CS-TB030	L
		MW-TBC15 INT HEX WP GH 1.5	MW-TBC15	L		C1 Conical Connection	WP	CW-TB001 C1 WP GH 0.5	CW-TB001	L
		MW-TBC30 INT HEX WP GH 3	MW-TBC30	L				CW-TB015 C1 WP GH 1.5	CW-TB015	L
BioHorizons								CW-TB030 C1 WP GH 3	CW-TB030	L

Table 6.1a- TiBase and Implant Compatibility Table as part of the Indications for Use

Proposed CEREC Tessera Abutment System					**Predicate CEREC Tessera Abutment Blocks, CEREC Tessera Abutment System (K221402)**				
Implant system		**Titanium base**			**Implant system**		**Titanium base**		
Manufacturer /line	**Platform**	**Name**	**REF**	**Size**	**Manufacturer/ line**	**Platform**	**Name**	**REF**	**Size**
Internal connection	3.0	TiBase BH 3.0 GH 1 S	6532779	S	SEVEN internal hex, M4 internal hex	NP	MN-TB001 INT HEX NP GH 0.5	MN-TB001	L
	3.5	TiBase BH 3.5 GH 1 L	6532894	L			MN-TBC15 INT HEX NP GH 1.5	MN-TBC15	L
	4.5	TiBase BH 4.5 GH 1 L	6532951	L		SP	MD-TB001 INT HEX SP GH 0.5	MD-TB001	L
	5.7	TiBase BH 5.7 GH 1 L	6536242	L			MD-TBC15 INT HEX SP GH 1.5	MD-TBC15	L
Nobel Biocare							MD-TBC30 INT HEX SP GH 3	MD-TBC30	L
Replace, Replace Select	NP	TiBase NB RS 3.5 GH 1 L	6282474	L		WP	MW-TB001 INT HEX WP GH 0.5	MW-TB001	L
	RP	TiBase NB RS 4.3 GH 1 L	6282482	L			MW-TBC15 INT HEX WP GH 1.5	MW-TBC15	L
	WP	TiBase NB RS 5.0 GH 1 L	6282490	L			MW-TBC30 INT HEX WP GH 3	MW-TBC30	L
	6.0	TiBase NB RS 6.0 GH 1 L	6282508	L					
Nobel Active NobelReplace Conical Connection	NP	TiBase NB A 4.5 GH 1 L	6308188	L					
	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					

Table 6.1a- TiBase and Implant Compatibility Table as part of the Indications for Use										
Proposed CEREC Tessera Abutment System						**Predicate CEREC Tessera Abutment Blocks, CEREC Tessera Abutment System (K221402)**				
Implant system		**Titanium base**				**Implant system**		**Titanium base**		
Manufacturer /line	**Platform**	**Name**	**REF**	**Size**		**Manufacturer/ line**	**Platform**	**Name**	**REF**	**Size**
	6	TiBase TM 6 GH 1 S	6544378	S						
Osstem / Hiossen										
Osstem TS (USA: Hiossen ET)	Mini	TiBase O TS 3.5 GH 1 L	6527035	L						
	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						
Straumann										
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						

Table 6.2 compares the Indications for Use of the proposed CEREC Tessera Abutment System and the reference devices, CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018), Dentsply Sirona Titanium Bases System (K250295), Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421).

The refence devices are all cleared as systems comprised of a block material, TiBases and CAD/CAM System. The main difference of the proposed CEREC Tessera Abutment System Indications for Use when compared to the reference devices is the Implant/TiBase compatibilities.

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems

Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
CEREC Tessera Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. For BH 3.0 S, NC Variobase C 3.3, Camlog 3.3 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: • CEREC Tessera Abutment Block • TiBase • CAD/CAM system	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	The Dentsply Sirona TiBase 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 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.
The CEREC Tessera Abutment 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 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 TiBase is recommended for use with two-piece hybrid abutments 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.

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
The compatible Implant systems, titanium bases and CAD/CAM systems are shown below:	Implant Systems: Dentsply Sirona: PrimeTaper EV, OmniTaper EV, AstraTech OsseoSpeed TX, Frialit / XiVE, AstraTech Implant EV, Ankylos	Implant Systems: Dentsply Sirona: AstraTech Implant EV, PrimeTaper EV, OmniTaper EV, AstraTech OsseoSpeed TX, Ankylos	The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646)
Implant Systems including DS TiBase: • Dentsply Sirona: AstraTech OsseoSpeed TX; Ankylos; • MIS: C1 Conical connection ; V3 Conical connection; SEVEN internal hex, M4 internal hex • BioHorizons: Internal Connection • Zimmer/Biomet: External Hex; Certain; Tapered Screw Vent • Nobel Biocare: Replace, Replace Select; Nobel Active, NobelReplace Conical Connection; Branemark; NobelSpeedy, Groovy • Straumann: Tissue Level; Bone Level • Thommen Medical: Element, Contact • Osstem/Hoisen: Osstem TS (USA: Hiosen ET) • Camlog: Camlog	• 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	• 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	• Nobel Biocare Branemark (K022562) • Friadent Xive (K001386) • Biomet 3i Osseotite (K980549) • AstraTech Osseospeed (K091239) • Zimmer Tapered Screw-Vent (K061410) • Straumann SynOcta (K061176) • Straumann Bone Level (K053088) • Biomet 3i Certain (K014235) • Nobel Biocare Active (K071370)
CAD/CAM Systems: • Sirona Dental CAD/CAM System	CAD/CAM Systems: • Sirona Dental CAD/CAM System	CAD/CAM Systems: • Sirona Dental 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.
Manufacturer: Dentsply Sirona Implant: AstraTech Osseospeed TX Platform: 3.5/4.0, TiBase AT TX 3.5/4.0 GH1 L; Reference: 6598093; Size L Platform: 4.5/5.0, TiBase AT TX 4.5/5.0 GH1 L; Reference: 6598101, Size L	Manufacturer: Dentsply Sirona 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: AstraTech 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;	

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
Platform: 3.5/4.0, TiBase AT OS 3.5/4.0 GH1 L; Reference: 6282532;Size L Platform: 4.5/5.0, TiBase ATOS 4.5/5.0 GH1 L; Reference: 6282540; Size L 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: M.I.S. Implants Implant: C1 Conical Connection Platform: NP; CN-TB001 C1 NP GH 0.5; Reference: CN-TB001; Size: L Platform: NP; CN-B015 C1 NP GH 1.5; Reference: CN-TB015; Size: L Implant: V3 Conical Connection Platform: NP; VN-TB001 V3 NP GH 0.5; Reference: VN-TB001; Size: L Platform: NP; VN-TB015 V3 NP GH 1.5; Reference: VN-TB015; Size: L Implant: V3 Conical Connection / C1 Conical Connection Platform: SP; CS-TB001 SP GH 0.5; Reference: CS-TB001; Size: L Platform: SP; CS-TB015 SP GH 1.5; Reference: CS-TB015; Size: L Platform: SP; CS-TB030 SP GH 3; Reference: CS-TB030; Size: L Implant: C1 Conical Connection Platform: WP; CW-TB001 C1 WP GH	Manufacturer: Dentsply Sirona 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: 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: AstraTech Implant EV Platform: XL; TiBase AT EV 5.4 GH 1 L; Reference: 66586346; 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	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: AstraTech 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: AstraTech 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	

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
0.5; Reference: CW-TB001; Size: L Platform: WP; CW-TB015 C1 WP GH 1.5; Reference: CW-TB015; Size: L Platform: WP; CW-TB030 C1 WP GH 3; Reference: CW-TB030; Size: L Implant: SEVEN internal hex, M4 internal hex Platform: NP; MN-TB001 INT HEX NP GH 0.5; Reference: MN-TB001; Size: L Platform: NP; MN-TBC15 INT HEX NP GH 1.5; Reference: MN-TBC15; Size: L Platform: SP; MD-TB001 INT HEX SP GH 0.5; Reference: MD-TB001; Size: L Platform: SP; MD-TBC15 INT HEX SP GH 1.5; Reference: MD-TBC15; Size: L Platform: SP; MD-TBC30 INT HEX SP GH 3; Reference: MD-TBC30; Size: L Platform: WP; MW-TB001 INT HEX WP GH 0.5; Reference MW-TB001; Size: L Platform: WP; MW-TBC15 INT HEX WP GH 1.5; Reference: MW-TBC15; Size: L Platform: WP; MW-TBC30 INT HEX WP GH 3; Reference: MW-TBC30; Size: L 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;	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	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	

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
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, Nobel Replace Conical Connection Platform: NP; TiBase NB A 4.5 GH 1 L; Reference: 6308188; Size: L 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	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;	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	

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
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: 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	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	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	

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
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: 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	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		

Table 6.2- Comparison of Indications for Use- Proposed and Referenced Systems			
Proposed CEREC Tessera Abutment System	**Reference Devices**		
	CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	**Dentsply Sirona Titanium Bases System (K250295)**	**Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)**
	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 Variobase 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		

7. Technological Comparison:

The CEREC Tessera Abutment System was cleared via K221402. There are no changes to the CEREC Tessera Abutment Block (K221402) material, use or technological properties. The purpose of this submission is to modify the system to add new TiBase and Implant compatibilities, update the minimum wall thickness and updates to the labeling.

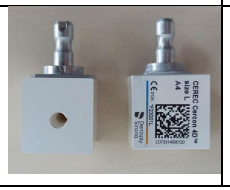
Table 7 details the technological characteristics for proposed CEREC Tessera Abutment System compared to the prior CERCE Tessera Abutment Block, CEREC Tessera Abutment System (K221402) and the reference devices.

Table 7 – Technological Characteristics of the proposed CEREC Tessera Abutment System compared to the predicate, CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)

Item of Comparison	Proposed device CEREC Tessera Abutment System	Predicate device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)	Reference Devices			Similarities and Differences
			CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	Dentsply Sirona Titanium Bases System (K250295)	Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)	
Product Code	NHA, PNP	NHA, PNP	NHA, PNP	NHA, PNP	NHA	The proposed, predicate and reference devices (K234018 and K250295) are cleared for the same product codes. The reference device (K111421) was only cleared by the FDA as a system under product code NHA.
Manufacturer	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Same
Abutment Angle	0° to 20°	0° to 20°	0° to 20°	0° to 20°	0° to 20°	Same
Restoration	Single Unit	Single Unit	Single Unit	Single Unit	Single Unit	Same
Block Material	Lithium Disilicate	Lithium Disilicate	Zirconia	Zirconia	Zirconia	The proposed and predicate block material are the same, lithium disilicate. The reference devices are zirconia material and are included to support the fatigue limits
Block Size	A14: 20.8mm x 15.9mm x 12.4mm A16: 20.8mm x 15.9mm x 17.0mm	A14: 20.8mm x 15.9mm x 12.4mm A16: 20.8mm x 15.9mm x 17.0mm	20.8 x 20.6 x 19.6mm Sizes for screw access channel options will be 'S' (small) and 'L'(large)	20.8 x 20.6 x 19.6mm Sizes for screw access channel options will be 'S' (small) and 'L'(large)	S, L	Similar is sizes for milling a single tooth restoration. All blocks have a "S" or "L" which relates to the connection of the TiBase.
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same

Sterilization Method	Steam Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization	Same
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Same
Wall Thickness	Minimum 0.5 mm based on new fatigue testing	Minimum 1.0 mm based on XiVE fatigue testing	Minimum 0.5 mm	Minimum 0.5 mm	Minimum 0.5 mm	The proposed submission is a medication to the predicate device to change to the minimum wall thickness

Table 7 – Technological Characteristics of the proposed CEREC Tessera Abutment System compared to the predicate, CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)

Item of Comparison	Proposed device CEREC Tessera Abutment System	Predicate device CEREC Tessera Abutment Block, CEREC Tessera Abutment System (K221402)	Reference Devices			Similarities and Differences
			CEREC Cercon 4D Abutment Block, CEREC Cercon 4D Abutment System (K234018)	Dentsply Sirona Titanium Bases System (K250295)	Sirona Dental CAD/CAM System (inCoris ZI meso) (K111421)	
						design parameter due to the discontinuation of XiVE Implant System. New fatigue testing included to support the compatibility of Implant/TiBase combinations with 0.5 mm wall thickness
Fatigue Testing	Meets ISO 14801:2016	Meets ISO 14801:2016	Meets ISO 14801:2016	Meets ISO 14801:2016	Meets ISO 14801:2016	The proposed, predicate and reference devices have comparable endurance levels per ISO 14801:2016
Software Verification	Meets internal software integration requirements	Meets internal software integration requirements	Meets internal software integration requirements	Meets internal software integration requirements	Meets internal software integration requirements	Same
Block Design						Same

8. Non-Clinical Tests Summary and Conclusion:

Performance Testing:

Non-clinical bench testing was performed on the proposed CEREC Tessera Abutment System in accordance with ISO 14801:2016 *Dentistry - Implants - Dynamic loading test for endosseous dental implants* to determine the fatigue limit of the proposed compatibilities. Historical data was also used to support the fatigue limits of the proposed compatibilities within the CEREC Tessera Abutment System. Reverse engineering for demonstrating compatibility of the subject abutments for use with third-party implant bodies from different OEMs was leveraged from the reference devices (K100152, K111421, K181520, K193408 and K200191).

MR Testing:

MR testing included by reference met the following requirements and supports the MR Conditional labeling of the CEREC Tessera Abutment System:

- 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 (including reverse engineering):

Software system verification confirmed that the maximum and minimum design parameters for the customizable two-piece CEREC Tessera Abutment System devices 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.

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. If the 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:

No additional biocompatibility testing was conducted for the proposed CEREC Tessera Abutment System with the additional TiBase and Implant System compatibilities that are being added and the change in wall thickness. There is no change in the block material from what was cleared under K221402.

Cleaning, Disinfection, and Sterilization Testing CEREC Tessera Abutment System:
No additional cleaning, disinfection and sterilization testing was conducted for the proposed CEREC Tessera Abutment System with the additional TiBase and Implant System compatibilities that are being added and the change in wall thickness. There is no change in the block material or processing the finished restoration from what was cleared under K221402.

9. Clinical Performance Data:
   No data from human clinical studies has been included to support the substantial equivalence of the proposed CEREC Tessera Abutment System.

10. Conclusion Regarding Substantial Equivalence:
    The proposed CEREC Tessera Abutment System is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The proposed CEREC Tessera Abutment System has the same intended use, incorporates the same fundamental technology, and has similar Indications for Use as the predicate CEREC Tessera Abutment Blocks, CEREC Tessera Abutment System (K221402).

    Dynamic fatigue testing to support the additional TiBase and Implant System compatibilities with a minimum wall thickness of 0.5 mm is provided and the results of this testing along with historical test results demonstrate that the proposed CEREC Tessera Abutment System performs as well as the predicate device. In addition labeling for MR Conditional is supported by MR testing included by reference. Software verification was performed following the same methods as the predicate device (K221402), which confirms that the CEREC Tessera Abutment System components are selectable with the two software systems (Sirona Dental CAD/CAM System with CEREC Chairside Software (K193408) and Sirona Dental CAD/CAM System with inLab Software (K200191)).

    The performance and safety data included in this premarket notification support a conclusion of substantial equivalence.