March 22, 2023

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

Re: K221402
Trade/Device Name: CEREC Tessera Abutment Block, 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: February 21, 2023
Received: February 21, 2023

Dear Courtney Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*

K221402

Device Name

CEREC Tessera Abutment Block, CEREC Tessera Abutment System

Indications for Use *(Describe)*

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 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 (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:

Implant system		**Titanium base**		
Manufacturer / line	**Platform**	**Name**	**REF**	**Size**
Dentsply Sirona Implants				
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 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	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 Prime Taper EV	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	XL	TiBase AT EV 5.4 GH1 L	6586346	L
Ankylos	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	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

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 Tessera Abutment System (K221402)

1. Submitter Information:

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

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Fax number: 717-849-4343

Date Prepared: March 22, 2023

2. Device Name:

- Proprietary Name: CEREC Tessera Abutment Block, CEREC Tessera Abutment System
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: II
- Product Code: NHA - Abutment, Implant, Dental Endosseous,
  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
IPS e.max® CAD Abutment Solution extra systems	K191382	Ivoclar Vivadent AG

Reference Devices:

Reference Device Name	510(k)	Company Name
CELTRA Press	K161269	Dentsply Sirona
Sirona Dental CAD/CAM Systems	K193408, K200191	Dentsply Sirona

4. Description of Device:

The proposed CEREC Tessera Abutment Blocks are intended for fabrication of single cement-retained restorations. The CEREC Tessera Abutment System is comprised of the proposed 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 ceramic structures are fabricated by milling the proposed CEREC Tessera Abutment Blocks. 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.

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.

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 (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:

Implant system		***Titanium base***		
Manufacturer / line	***Platform***	***Name***	***REF***	***Size***
Dentsply Sirona Implants				
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 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	*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 *Prime Taper EV*	*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	*XL*	*TiBase AT EV 5.4 GH1 L*	*6586346*	*L*
Ankylos	*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	*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*

6. Substantial Equivalence:

For the purpose of substantial equivalence, the proposed CEREC Tessera Abutment System is compared to the legally marketed predicate device IPS e.max® CAD Abutment Solutions- extra systems marketed by Ivoclar Vivadent AG cleared under premarket notification K191382 on August 26, 2019. The proposed and predicate device (K191382) share the same intended use, similar indications for use, and product code information. Table 6.1 includes a comparison of the proposed and predicate devices.

The proposed CEREC Tessera Abutment System is compatible with additional implants system when compared to the predicate device, IPS e.max CAD Abutment Solution-extra systems (K191382). 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. Dentsply Sirona owns the engineering drawing and fatigue data of all compatible implant systems and also have clearance for these implant systems under the Sirona Dental CAD/CAM System (K193408, K200191).

Additionally, Dentsply Sirona's CELTRA Press (K161269) and Sirona Dental CAD/CAM Systems (K193408, K200191) are being included as a reference device for comparison of material composition and characteristics to support the substantial equivalence of the proposed CEREC Tessera Abutment Blocks as well compatibility with the Sirona Dental CAD/CAM systems. Table 6.2 includes a comparison of the proposed and reference devices.

Table 6.1: Comparison table between the proposed CEREC Tessera Abutment System and IPS e.max® CAD Abutment Solutions- extra systems (K191382)			
Characteristics	**Proposed CEREC Tessera Abutment System**	**IPS e.max® CAD Abutment Solutions- extra systems Predicate Device (K191382)**	**Similarities and Differences**
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.	IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.	Same intended use.
Indications for Use	The system comprises three parts: - CEREC Tessera Abutment Block - TiBase - CAD/CAM system.	The system comprises three parts: - IPS e.max CAD ceramic structure - Ti base - CAD/CAM system.	Similar, minor difference in wording. The predicate device describes the ceramic component as a "ceramic structure" whereas the proposed device is described as a block, "CEREC Tessera Abutment Block". The proposed device is described as a block, which is utilized to mill a single unit restoration, which is known as a ceramic structure.
Indications for Use	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 IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.	Same

<table>
<tr><th colspan="4"><u>Table 6.1</u>: Comparison table between the proposed CEREC Tessera Abutment System and IPS e.max® CAD Abutment Solutions- extra systems (K191382)</th></tr>
<tr><th>Characteristics</th><th>Proposed CEREC Tessera Abutment System</th><th>IPS e.max® CAD Abutment Solutions- extra systems Predicate Device (K191382)</th><th>Similarities and Differences</th></tr>
<tr><td>Compatible Materials</td><td>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)</td><td>The compatible Implant systems, titanium bases and CAD/CAM systems are shown below:

-Implant Systems:
- Dentsply Sirona: AstraTech OsseoSpeed, Frialit/Xive (K130999, K013867)
- BioHorizons Implant System: Internal Connection (K143022, K071638, K093321, K042429)
- Osstem: TS Implant System (K121585)
- Straumann: Tissue Level RN/WN (K061176)
- Nobel Biocare: Branemark (K022562)
- Zimmer: Tapered Screw-Vent (K061410)
- Camlog: Camlog Screw-Line, Conelog Screw-Line, iSy (K083496, K113779, K133991)</td><td>-The proposed CEREC Tessera Abutment System and the predicate device IPS e.max® CAD Abutment Solutions- extra systems (K191382) are intended for use with compatible TiBase and implant systems. Similarities and differences are described below :
<table><tr><th>Name</th><th>Proposed Device</th><th>Predicate Device</th></tr><tr><td>AstraTech OsseoSpeed</td><td>Compatible with AstraTech OsseoSpeed TX</td><td>Compatible with AstraTech OsseoSpeed</td></tr><tr><td>XiVE</td><td>Compatible</td><td>Compatible</td></tr><tr><td>Frialit</td><td>Not listed</td><td>Compatible</td></tr><tr><td>AstraTech Implant EV / PrimeTaper EV</td><td>Compatible</td><td>Not listed</td></tr><tr><td>Ankylos</td><td>Compatible</td><td>Not listed</td></tr><tr><td>MIS C1, V3, SEVEN, M4</td><td>Compatible</td><td>Not listed</td></tr><tr><td>BioHorizons, Osstem, Straumann, Nobel Biocare: Branemark, Zimmer, Camlog</td><td>Not listed</td><td>Compatible</td></tr></table></td></tr>
</table>

Table 6.1: Comparison table between the proposed CEREC Tessera Abutment System and IPS e.max® CAD Abutment Solutions- extra systems (K191382)			
Characteristics	**Proposed CEREC Tessera Abutment System**	**IPS e.max® CAD Abutment Solutions- extra systems Predicate Device (K191382)**	**Similarities and Differences**
CAD/CAM Systems	CAD/CAM Systems: -Sirona Dental CAD/CAM System (CEREC-K193408, inLab-K200191)	CAD/CAM Systems: Sirona Dental CAD/CAM System (K181520)	-Both the proposed CEREC Tessera Abutment and the predicate device IPS e.max® CAD Abutment Solutions- extra systems (K191382) are indicated for use with the Sirona Dental CAD/CAM System with CEREC chairside software (Pre-market clearance K193408 represents an update to Dentsply Sirona CAD/CAM system cleared under K181520). -The proposed CEREC Tessera Abutment system can also be used with Inlab software (K200191).
Product Code	NHA, PNP	NHA, PNP	Same
Manufacturer	Dentsply Sirona	Ivoclar Vivadent, AG	Different manufacturer
Abutment Angle	0° to 20°	0° to 20°	Same
Restoration	Single Unit	Single Unit	Same
Block Material	Lithium Disilicate	Lithium Disilicate	Same

Table 6.1: Comparison table between the proposed CEREC Tessera Abutment System and IPS e.max® CAD Abutment Solutions- extra systems (K191382)			
Characteristics	**Proposed CEREC Tessera Abutment System**	**IPS e.max® CAD Abutment Solutions- extra systems Predicate Device (K191382)**	**Similarities and Differences**
Cement (Adhesive)	Calibra Cement	Multilink Hybrid Abutment	The proposed device is recommended for use with Calibra Cement while the predicate device recommends Multilink Hybrid Abutment cement. The role of the cement is to glue the crown or meso-structure to the TiBase.
Sterility	Non-Sterile	Non-Sterile	Same
Sterilization Method	Steam Sterilization	Steam Sterilization	Same
Flexural Strength (ISO 6872)	Average of 705 MPa	≥ 360 MPa (K132209)	The proposed device has higher flexural strength than the predicate device.
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Both the proposed and predicate devices meet the criteria of ISO 10993
Fatigue	Meets ISO 14801	Meets ISO 14801	Both the proposed and predicate devices have comparable properties per ISO 14801
Software	Meets internal software integration requirements for addition the proposed device CEREC Tessera Abutment Block	Information unavailable for the predicate devices	The proposed CEREC Tessera Abutment Block has been integrated into Sirona CAD/CAM System software (K193408, K200191).

Table 6.1: Comparison table between the proposed CEREC Tessera Abutment System and IPS e.max® CAD Abutment Solutions- extra systems (K191382)			
Characteristics	**Proposed CEREC Tessera Abutment System**	**IPS e.max® CAD Abutment Solutions- extra systems Predicate Device (K191382)**	**Similarities and Differences**
MRI Safety Labeling	The subject device is labeled MRI Conditional	Unavailable	MRI test data leveraged from K221094

Although the proposed and the predicate IPS e.max® CAD Abutment Solutions- extra systems (K191382) are composed of Lithium Disilicate glass ceramic structure material, the exact formulation of the predicate ceramic structure material (K191382) is not available. Therefore, reference device CELTRA Press (K161269) is included to support the technological material characteristics of the proposed CEREC Tessera Abutment Block.

The proposed CEREC Tessera Abutment Block is identical in formulation to the reference device CELTRA Press (K161269). The material of the proposed device and the reference device (K161269) meets the performance requirements of ISO 6872:2015 (Amd 1. 2018), *Dentistry – Ceramic Materials* and FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".*

Table 6.2: Comparison of technological characteristics of the proposed CEREC Tessera Abutment Block with reference device CELTRA Press (K161269)			
Characteristics	**Proposed CEREC Tessera Abutment Block**	**Reference CELTRA Press (K161269)**	**Similarities and Differences**
Formulation	Lithium disilicate	Lithium disilicate	Same
ISO 6872:2015 Amd 1. 2018	Meets criteria defined in ISO 6872	Meets criteria defined in ISO 6872	Same, meets criteria defined in ISO 6872

7. Non-Clinical Performance Data

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* and on the proposed CEREC Tessera Abutment Block per ISO 6872:2015 Amd 1. 2018 *Dentistry – Ceramic Materials*.

Biocompatibility Testing:

Biocompatibility evaluation assessment for the proposed device CEREC Tessera Abutment Block was performed according to ISO 10993-1:2020 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. The proposed CEREC Tessera Abutment Block has the same composition, patient contact point and duration of use as the reference device, CELTRA Press (K161269), which was assessed and tested for biological safety, and does not raise additional questions of safety or effectiveness. A confirmatory cytotoxicity test per 10993-5, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* was performed with satisfactory results.

The performance of the proposed CEREC Tessera Abutment Block satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Cleaning, Disinfection, and Sterilization Testing CEREC Tessera Abutment System:

The manual and automated cleaning process and the automated disinfection processes were validated according to

- *ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the Processing of medical devices, and*
- *ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document issued on: March 17, 2015*
- *AAMI TIR-12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*

In addition, the sterilization process was validated using a hybrid method to ensure that the proposed device can be steam sterilized at 132º C for 4 minutes and 135º C for 3 minutes and achieve a Sterility Assurance Level (SAL) of 10^{-6}. In addition to the above standards and guidance documents, sterilization test results also met the criteria of ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, 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*, and ISO 17665-2 *Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1*.

8. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the proposed CEREC Tessera Abutment Blocks or CEREC Tessera Abutment System.

9. 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 device CEREC Tessera Abutment System has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate IPS e.max® CAD Abutment Solutions- extra systems (K191382). Test data to verify the performance of the proposed device was provided including dynamic fatigue testing and physical properties and the results of this testing, combined with the design and indications for use comparison with the predicate device, support substantial equivalence.