August 16, 2020

Dentsply Sirona
Karl Nittinger
Vice President, Corporate Regulatory Affairs
221 West Philadelphia St., Suite 60W
York, Pennsylvania 17401

Re: K193408
Trade/Device Name: Sirona Dental CAD/CAM System with CEREC Chairside Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: July 16, 2020
Received: July 17, 2020

Dear Karl Nittinger:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193408

Device Name

Sirona Dental CAD/CAM System with CEREC Chairside Software

Indications for Use *(Describe)*

The Sirona Dental CAD/CAM System with CEREC Chairside Software is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the AT TX 3.0 S, BH 3.0 S, SSO 3.5 L, and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two- piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.XXXX) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:

Manufacturer	**Name of Implant System**	**Implant Size**	
		Platform	**Diameter**
Nobel Biocare	Replace	NP	3.5
		RP	4.3
		WP	5.0
		6.0	6.0
	Active	NP	3.5
		RP	4.3/5.0
	Branemark	NP	3.3
		RP	3.75/4.0
Straumann	Synocta	NN (3.5mm)	3.3
		RN (4.8mm)	3.3/4.1/4.8
		WN (6.5mm)	4.8
	Bone Level	NC (3.3mm)	3.3
		RC (4.1mm/4.8mm	4.1/4.8
Dentsply Sirona Implants	Osseospeed	3.5/4.0	3.5 S / 4.0 S
		4.5/5.0	4.5/5.0/5.0 S
	Xive	3.4	3.4
		3.8	3.8
		4.5	4.5
		5.5	5.5

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Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
Dentsply Sirona Implants	Osseospeed EV	3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Ankylos	C/X	A, B, C, D
	Osseospeed TX	3.0	3.0
		3.5/4.0	3.5/4.0
		4.5/5.0	4.5/5.0
Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75
			4.1
			3/4
		5.0	5.0
			4/5
	Certain	3.4	3.25
			4/3
			3/4/3
		4.1	4.0
			4/5/4
			5/4
		5.0	5.0
			4/5
Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
		4.5	4.7
		5.7	6
Thommen Medical	Thommen Medical Implants	3.5	3.5
		4	4
		4.5	4.5
		5	5
		6	6
Osstem / Hiossen	Osstem TS Implant System Hiossen Implant System	Mini	3.5
		Regular	4.0/4.5/5.0/6.0/7.0

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
BioHorizons (Internal Connection)	Tapered 3.0,Tapered plus	3.0	3.0/3.4/3.8
	Tapered internal		3.0
	Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5
	Single stage dental implants		3.5/4.0
	Tapered Plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0
	Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0

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
Sirona Dental CAD/CAM System with CEREC Chairside Software (K193408)

1. Submitter Information**:**

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

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343
Email: karl.nittinger@dentsplysirona.com

Date Prepared: 11 August 2020

2. Device Name:

- Proprietary Name: Sirona Dental CAD/CAM System with CEREC Chairside Software
- Classification Name: Endosseous dental implant abutment.
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Primary Product Code: NHA (*Abutment, Implant, Dental Endosseous*)
- Secondary Product Code: PNP (*Dental Abutment Design Software for Dental Laboratory)*

3. Predicate Device:

The predicate device that has been identified relating to the substantial equivalence of the Sirona Dental CAD/CAM System with CEREC Chairside Software is:

Primary Predicate Device Name	**510(k)**	**Company Name**
Sirona Dental CAD/CAM System	K181520	Sirona Dental Systems GmbH (Dentsply Sirona)
Reference Device Name		
Osseospeed TX implant (3.5, 4.0, 4.5, 5.0)	K080156	Astra Tech AB (Dentsply Sirona)
Osseospeed TX Implant (3.0)	K080396	Astra Tech AB (Dentsply Sirona)

4. Description of Device:

The Sirona Dental CAD/CAM System with CEREC Chairside Software which is the subject of this premarket notification is a modification to the Sirona Dental CAD/CAM System as previously cleared under K181520. The modified Sirona Dental CAD/CAM System with CEREC Chairside Software that is the subject of this premarket notification includes a line extension to the existing offerings. These additional TiBase variants facilitate compatibility with currently marketed dental implant systems.

The modified Sirona Dental CAD/CAM System with CEREC Chairside Software which is the subject of this premarket notification consists of:

- CEREC SW "chairside" CAD/CAM software
- CEREC AC digital acquisition unit
- CEREC AC Connect digital acquisition unit
- CEREC Omnicam 3D digital intraoral scanner
- CEREC MCXL product family of CAM milling units
- **Additional Sirona TiBase titanium base components (line extension subject to this submission) compatible with Dentsply Sirona Osseospeed TX 3.0, 3.5, 4.0, 4.5, and 5.0 implants.**
- inCoris ZI zirconium mesostructure blocks

As subject to this premarket notification, the Sirona Dental CAD/CAM System with CEREC Chairside Software is utilized to digitally acquire and record the topographical characteristics of teeth, dental impressions, or physical stone models in order to facilitate the computer aided design (CAD) and computer aided manufacturing (CAM) of two-piece "CAD/CAM" abutments. The patient-specific two-piece abutments consist of prefabricated "TiBase" components which are designed with interface geometry to facilitate compatibility and connection with currently marketed dental implant system.

As subject to this premarket notification, the subject Sirona Dental CAD/CAM System with CEREC Chairside Software is modified to include a line extension to the existing TiBase offerings by introducing TiBases which are compatible with the Dentsply Sirona Osseospeed TX 3.0, 3.5, 4.0, 4.5, and 5.0 dental implants.

The CEREC SW CAD/CAM software is utilized to drive the specified acquisition unit hardware to acquire the intraoral dental scans and to design the mesostructure component of the CAD/CAM abutments. Following the completion of the design, the CEREC SW drives the CAM fabrication of the mesostructure component in the "chairside" workflow by utilizing the CEREC MCXL milling equipment and the defined zirconium/zirconia block materials.

The Sirona Dental CAD/CAM System with CEREC Chairside Software is intended for the design and fabrication of two-piece, CAD/CAM dental abutments.

5. Indications for Use:

The Sirona Dental CAD/CAM System with CEREC Chairside Software is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the AT TX 3.0 S, BH 3.0 S, SSO 3.5 L, and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two- piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two- piece abutment is compatible with the following implant systems:

Manufacturer	**Name of Implant System**	**Implant Size**	
		Platform	**Diameter**
Nobel Biocare	Replace	NP	3.5
		RP	4.3
		WP	5.0
		6.0	6.0
	Active	NP	3.5
		RP	4.3/5.0
	Branemark	NP	3.3
		RP	3.75/4.0
Straumann	Synocta	NN (3.5mm)	3.3
		RN (4.8mm)	3.3/4.1/4.8
		WN (6.5mm)	4.8
	Bone Level	NC (3.3mm)	3.3
		RC (4.1mm/4.8mm	4.1/4.8
Dentsply Sirona Implants	Osseospeed	3.5/4.0	3.5 S / 4.0 S
		4.5/5.0	4.5/5.0/5.0 S
	Xive	3.4	3.4
		3.8	3.8
		4.5	4.5
		5.5	5.5

Manufacturer	Name of Implant System	Implant Size	
		Platform	**Diameter**
Dentsply Sirona Implants	Osseospeed EV	3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Ankylos	C/X	A, B, C, D
	Osseospeed TX	**3.0**	**3.0**
		3.5/4.0	**3.5/4.0**
		4.5/5.0	**4.5/5.0**
Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75
			4.1
			3/4
		5.0	5.0
			4/5
	Certain	3.4	3.25
			4/3
			3/4/3
		4.1	4.0
			4/5/4
			5/4
		5.0	5.0
			4/5
Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
		4.5	4.7
		5.7	6
Thommen Medical	Thommen Medical Implants	3.5	3.5
		4	4
		4.5	4.5
		5	5
		6	6
Osstem / Hiossen	Osstem TS Implant System Hiossen Implant System	Mini	3.5
		Regular	4.0/4.5/5.0/6.0/7.0

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
BioHorizons (Internal Connection)	Tapered 3.0,Tapered plus	3.0	3.0/3.4/3.8
	Tapered internal		3.0
	Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5
	Single stage dental implants		3.5/4.0
	Tapered Plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0
	Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0

6. Substantial Equivalence:

The modified Sirona Dental CAD/CAM System with CEREC Chairside Software has the same intended use as the predicate Sirona Dental CAD/CAM System cleared under premarket notification K181520. Both the modified Sirona Dental CAD/CAM System with CEREC Chairside Software and the predicate device are intended as optical impression systems for the 3D digital acquisition of the topography of teeth for use in the design and manufacturing of two-piece "CAD/CAM" dental abutments. As such, the subject Sirona Dental CAD/CAM System with CEREC Chairside Software and the predicate device cleared under premarket notification K181520 are regulated under 21 CFR 872.3630.

Osseospeed TX implant (K080156 and K080396) is listed as a reference device for the purpose of showing clearance of the additional implant system that the modified Sirona Dental CAD/CAM System with CEREC Chairside Software is compatible with. The previously cleared reference device, Osseospeed TX implant (K080156 and K080396) is not changed in any aspect (e.g. diameter) under the scope of this submission.

The modified Sirona Dental CAD/CAM System with CEREC Chairside Software which is the subject of this premarket notification and the predicate cleared under premarket notification K181520 include the same scanning, acquisition, and milling equipment, and utilize the same TiBase and inCoris ZI zirconia mesostructure materials for the design and fabrication of two-piece, CAD/CAM dental abutments.

The primary differences between the modified Sirona Dental CAD/CAM System with CEREC Chairside Software and the predicate device cleared in K181520 is the line extension of the available variants of the existing Sirona TiBase titanium base component offerings to facilitate compatibility with an additional dental implant system (Osseospeed TX).

Summary comparison of the intended use, indications for use, and design of the modified Sirona Dental CAD/CAM System with CEREC Chairside Software and the predicate, Sirona Dental CAD/CAM System (K181520), is presented in Tables 6.1 and 6.2.

Table 6.1: Indications for Use

Modified Device **Sirona Dental CAD/CAM System with CEREC Chairside Software**	**Predicate Device** **Sirona Dental CAD/CAM System (K181520)**
The Sirona Dental CAD/CAM System with CEREC Chairside Software is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the AT TX 3.0 S, BH 3.0 S, SSO 3.5 L and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:	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. For the BH 3.0 S, SSO 3.5 L and SBL 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructures may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:

Manufacturer	Name of Implant System	Implant Sizes	
		Platform	**Diameter**
Nobel Biocare	Replace	NP	3.5
		TP	4.3
		WP	5.0
		6.0	6.0
	Active	NP	3.5
		RP	4.3/5.0
	Branemark	NP	3.3
		RP	3.75/4.0
Straumann	Synocta	NN (3.5mm)	3.3
		RN (4.8mm)	3.3/4.1/4.8
		WN (6.5mm)	4.8
	Bone Level	NC (3.3mm)	3.3
		RC (4.1mm/4.8mm)	4.1/4.8
Dentsply Sirona Implants	Osseospeed	3.5/4.0	3.5 S / 4.0 S
		4.5/5.0	4.5/5.0/5.0 S
	Xive	3.4	3.4
		3.8	3.8
		4.5	4.5
		5.5	5.5
	Osseospeed EV	3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Ankylos	C/X	A, B, C, D
	Osseospeed TX	**3.0**	**3.0**
		3.5/4.0	**3.5/4.0**
		4.5/5.0	**4.5/5.0**
Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75
			4.1
			3/4
		5.0	5.0
			4/5
	Certain	3.4	3.25
			4/3
			3/4/3
		4.1	4.0
			4/5/4
			5/4
		5.0	5.0
			4/5
Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
		4.5	4.7
		5.7	6
Thommen Medical	SPI ELEMENT, SPI ELEMENT INICELL, SPI	4	4
		4.5	4.5
		5	5
		6	6

Manufacturer	Name of Implant System	Implant Sizes	
		Platform	**Diameter**
Nobel Biocare	Replace	NP	3.5
		TP	4.3
		WP	5.0
		6.0	6.0
	Active	NP	3.5
		RP	4.3/5.0
	Branemark	NP	3.3
		RP	3.75/4.0
Straumann	Synocta	NN (3.5mm)	3.3
		RN (4.8mm)	3.3/4.1/4.8
		WN (6.5mm)	4.8
	Bone Level	NC (3.3mm)	3.3
		RC (4.1mm/4.8mm)	4.1/4.8
Dentsply Sirona Implants	Osseospeed	3.5/4.0	3.5 S / 4.0 S
		4.5/5.0	4.5/5.0/5.0 S
	Xive	3.4	3.4
		3.8	3.8
		4.5	4.5
		5.5	5.5
	Osseospeed EV	3.6	3.6
		4.2	4.2
		4.8	4.8
		5.4	5.4
	Ankylos	C/X	A, B, C, D
Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75
			4.1
			3/4
		5.0	5.0
			4/5
	Certain	3.4	3.25
			4/3
			3/4/3
		4.1	4.0
			4/5/4
			5/4
		5.0	5.0
			4/5
Zimmer	Tapered Screw-Vent	3.5	3.7/4.1
		4.5	4.7
		5.7	6
Thommen Medical	SPI ELEMENT, SPI ELEMENT INICELL, SPI CONTACT INICELL	4	4
		4.5	4.5
		5	5
		6	6

	CONTACT INICELL		
Manufacturer	**Name of Implant System**	**Implant Sizes**	
		Platform	**Diameter**
Osstem / Hiossen	Osstem TS Implant System-Hiossen Implant System	Mini	3.5
		Regular	4.0/4.5/5.0/6.0/7.0
BioHorizons (Internal Connection)	Tapered 3.0, Tapered plus	3.0	3.0/3.4/3.8
	Tapered Internal		3.0
	Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5
	Single stage dental implants		3.5/4.0
	Tapered plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0
	Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0

Osstem / Hiossen	Osstem TS Implant System-Hiossen Implant System	Mini	3.5
		Regular	4.0/4.5/5.0/6.0/7.0
Manufacturer	**Name of Implant System**	**Implant Sizes**	
		Platform	**Diameter**
BioHorizons (Internal Connection)	Tapered 3.0, Tapered plus	3.0	3.0/3.4/3.8
	Tapered Internal		3.0
	Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5
	Single stage dental implants		3.5/4.0
	Tapered plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0
	Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0

Table 6.2: Design

Modified Device **Sirona Dental CAD/CAM System with CEREC Chairside Software**	**Predicate Device** **Sirona Dental CAD/CAM System (K181520)**
CAD/CAM Software Version	
CEREC SW Chairside CAD/CAM Software	CEREC SW Chairside CAD/CAM Software
Acquisition Units	
CEREC AC	CEREC AC
CEREC AC Connect	CEREC AC Connect
CEREC Omnicam 3D digital intraoral scanner	CEREC Omnicam 3D digital intraoral scanner
Milling Unit	
CEREC MC	CEREC MC
CEREC MC X	CEREC MC X
CEREC MC XL	CEREC MC XL
CEREC MC XL Premium	CEREC MC XL Premium
Titanium Base Components	
Sirona TiBase Diameter: 3.0 mm – 7.0 mm	Sirona TiBase Diameter: 3.0 mm – 7.0 mm
Maximum Angulation of Finished Abutment: 20°	Maximum Angulation of Finished Abutment: 20°
Material (TiBase and Screw) Titanium alloy	Material (TiBase and Screw) Titanium alloy
Mesostructure material	
Sirona inCoris ZI zirconium blocks	Sirona inCoris ZI zirconium blocks
Block Material: Zirconium oxide ceramic	Block Material: Zirconium oxide ceramic
Block Dimensions: 24 mm (L) x 23 mm (W) x 21.5 mm (H)	Block Dimensions: 24 mm (L) x 23 mm (W) x 21.5 mm (H)
Available Shades: F0.5, F2	Available Shades: F0.5, F2

7. Non-Clinical Performance Data

Testing to verify the performance requirements of the modified Sirona Dental CAD/CAM System with CEREC Chairside Software was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification:

- Geometric compatibility of the implant to the TiBase connection implant connection interface is confirmed for the subject new Sirona TiBase components via direct access to the original manufacturer's implant geometry specifications for the Dentsply Sirona, OsseoSpeed TX implant system. Because the implant to TiBase interface connection geometry of the proposed Sirona TiBase component for this system was designed through direct reference to the original implant design specifications, no reverse engineering analysis was conducted.

- Dynamic fatigue testing of new TiBase variants in worst-case construct according to ISO 14801 (*Dentistry - Implants - Dynamic loading test for endosseous dental implants*) was conducted. The test design included test sample constructs fabricated at the maximum allowable abutment angulation and utilizing TiBase components exhibiting the worst-case design with respect to implant connection interface geometry.

- New TiBase variants are composed of the identical materials and are fabricated utilizing the same methods as the components cleared under K181520. Therefore, no new biocompatibility data is included to support the substantial equivalence of the modified Sirona Dental CAD/CAM System.

- The recommended steam sterilization parameters for the new TiBase components included in the line extension as subject to this premarket notification are identical to the validated steam sterilization parameters recommended for the TiBase components included with the predicate device as cleared under premarket notification K181520. The validation of the recommended steam sterilization parameters was conducted according to 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 with reference to ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 and A4:2013: *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* and the original validation of the recommended parameters is referenced in this premarket notification in support of substantial equivalence.

- Software system integration testing was conducted to validate the system requirements associated with the introduction of the TiBase component line extension as selectable within the CEREC Chairside CAD/CAM software for the design and fabrication of two-piece CAD/CAM dental abutments. No modification to the CEREC CAD/CAM abutment design software's controls limiting the critical abutment design parameters are introduced in this premarket notification.

8. Clinical Performance Data

No human clinical data was included in this premarket notification to support the substantial equivalence of the modified Sirona Dental CAD/CAM System with CEREC Chairside Software.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the modified Sirona Dental CAD/CAM System with CEREC Chairside Software. The modified device which is the subject of this premarket notification has the identical intended use as the legally marketed predicate device cleared under premarket notification K181520. The modified device also has similar indications for use and incorporates the same fundamental technology as the predicate device (K181520).

Performance testing was conducted to demonstrate the performance of the modified Sirona Dental CAD/CAM System with CEREC Chairside Software with the line extension of the TiBase offerings. The results of the testing included in this premarket notification support a determination of substantial equivalence with the additional TiBases offered.