October 11, 2018

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

Re: K181520
Trade/Device Name: Sirona Dental CAD/CAM System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: September 7, 2018
Received: September 10, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K181520

Device Name

Sirona Dental CAD/CAM System

Indications for Use *(Describe)*

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 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
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	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

SECTION 5. 510(k) SUMMARY
for
Sirona Dental CAD/CAM System

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

Date Prepared: 11-October-2018

2. Device Name:

- Proprietary Name: Sirona Dental CAD/CAM System
- 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 and Reference Devices:

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

Predicate Device	**510(k)**	**Company Name**
Sirona Dental CAD/CAM System	K111421	Sirona Dental Systems GmbH

Reference Devices:

Reference Device	Manufacturer	510(k) Clearance
TS Implant System	Osstem Implant Co., Ltd.	K121585
Hiossen Implant System	Hiossen, Inc.	K140934, K101096
SPI Element, SPI Element INICELL, SPI Contact INICELL	Thommen Medical AG	K093615, K090154
Osseospeed EV (AT EV) Implants	Dentsply Sirona Implants	K130999
Ankylos C/X Implant System	Dentsply Sirona Implants	K140347, K083805
BioHorizons Implant System (internal connection)	BioHorizons Implant Systems, Inc.	K143022, K071638, K093321, K042429
IPS e.max CAD Abutment Solutions	Ivoclar Vivadent AG	K132209
Telio CAD Abutment Solutions	Ivoclar Vivadent AG	K151564
VITA ENAMIC IS	Vita Zahnfabrik H. Rauter GmbH Co.	K153564

4. Description of Device:

The Sirona Dental CAD/CAM System which is the subject of this premarket notification is a modification to the Sirona Dental CAD/CAM System as previously cleared under K111421. The modifications represented in the subject device consist of the implementation of a new "chairside" CAD/CAM software version, CEREC SW version 4.6.1, in which additional functionality for the control of critical CAD/CAM abutment dimensions has been added.

Additionally, the modified Sirona Dental CAD/CAM System that is the subject of this premarket notification includes a line extension to the existing offerings of the Sirona TiBase titanium base component offerings. These additional TiBase variants facilitate compatibility with additional implant systems.

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

- CEREC SW version 4.6.1, "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
- Sirona TiBase titanium base components
- inCoris ZI zirconium mesostructure blocks

As subject to this premarket notification, the Sirona Dental CAD/CAM System 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 pre-fabricated "TiBase" components which are designed with interface geometry to facilitate compatibility and connection with currently marketed dental implant system.

The CEREC SW 4.6.1 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 4.6.1 drives the CAM fabrication of the mesostructure component in the "chairside" workflow by utilizing the CEREC MCXL milling equipment and the defined zirconium block materials. The completed mesostructure is cemented to the TiBase component using PANAVIA F 2.0 dental cement in order to complete the finished, two-piece CAD/CAM dental abutment.

5. Indications for Use:

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 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
	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

Manufacturer	Name of Implant System	Implant Size	
		Platform	Diameter
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	3.5	3.5
		4	4
		4.5	4.5
		5	5
		6	6
Osstem/Hiossen	Osstem TS Implant System	Mini	3.5
	Hiossen Implant System	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

6. Substantial Equivalence:

The modified Sirona Dental CAD/CAM System has the same intended use as the predicate Sirona Dental CAD/CAM System cleared under premarket notification K111421. Both the modified Sirona Dental CAD/CAM System 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 and the predicate device cleared under premarket notification K111421 are regulated under 21 CFR 872.3630.

The modified Sirona Dental CAD/CAM System which is the subject of this premarket notification and the predicate cleared under premarket notification K111421 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 and the predicate device cleared in K111421 are the implementation under this premarket notification of the new version of the CAD/CAM "chairside" software, the CEREC SW version 4.6.1, and the extension of the available variants of the existing Sirona TiBase titanium base component offerings to facilitate compatibility with additional dental implant systems.

As subject to this premarket notification, the indications for use of the Sirona CAD/CAM System have been modified relative to the expansion of implant systems to which the new TiBase component offerings are compatible (i.e., the addition of Osstem, Hiossen, Thommen Medical, BioHorizons, and Dentsply Sirona Osseospeed EV and Ankylos C/X implant systems).

In addition, the format of the listing of all compatible implant systems in the indications for use has been modified in this premarket notification to provide further detailed information regarding the specific implant system name, implant platform size, and diameter for each of the compatible implant systems. This clarification to the compatibility list has been made to conform to current indications for use for clear identification of compatible implant systems.

The new "chairside" CAD/CAM software version, CEREC SW version 4.6.1 includes the introduction of revised software controls over the limitation of critical geometric parameters in the design of the mesostructure component of two-piece, "CAD/CAM" dental abutments.

Summary comparison of the intended use, indications for use, and design of the modified Sirona Dental CAD/CAM System and the predicate Sirona Dental CAD/CAM System cleared under K111421 is presented in Tables 6.1 and 6.2.

Table 6.1: Indications for Use

<table>
<tr><th colspan="4"><u>Modified Device</u>
Sirona Dental CAD/CAM System</th><th><u>Predicate Device</u>
Sirona Dental CAD/CAM System (K111421)</th></tr>
<tr><td colspan="5">Indications for Use</td></tr>
<tr><td colspan="4">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:</td><td>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 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:</td></tr>
<tr><td rowspan="2">Manufacturer</td><td rowspan="2">Implant System</td><td colspan="2">Implant Size</td><td rowspan="2">Manufacturer</td></tr>
<tr><td>Platform</td><td>Diameter</td></tr>
<tr><td rowspan="8">Nobel Biocare</td><td rowspan="4">Replace</td><td>NP</td><td>3.5</td><td>● Nobel Biocare Replace (K020646)</td></tr>
<tr><td>RP</td><td>4.3</td><td>● Nobel Biocare Branemark (K022562)</td></tr>
<tr><td>WP</td><td>5.0</td><td>● Friadent Xive (K013867)</td></tr>
<tr><td>6.0</td><td>6.0</td><td>● Biomet 3i Osseotite (K980549)</td></tr>
<tr><td rowspan="2">Active</td><td>NP</td><td>3.5</td><td>● Astra Tech Osseospeed (K091239)</td></tr>
<tr><td>RP</td><td>4.3/5.0</td><td>● Zimmer Tapered Screw-Vent (K061410)</td></tr>
<tr><td rowspan="2">Branemark</td><td>NP</td><td>3.3</td><td>● Straumann SynOcta (K061176)</td></tr>
<tr><td>RP</td><td>3.75/4.0</td><td>● Straumann Bone Level (K053088, K062129, K060958)</td></tr>
<tr><td rowspan="5">Straumann</td><td rowspan="3">Synocta</td><td>NN (3.5mm)</td><td>3.3</td><td>● Biomet 3i Certain (K014235, K061629)</td></tr>
<tr><td>RN (4.8mm)</td><td>3.3/4.1/4.8</td><td>● Nobel Biocare Active (K071370)</td></tr>
<tr><td>WN (6.5mm)</td><td>4.8</td><td rowspan="9"></td></tr>
<tr><td rowspan="2">Bone Level</td><td>NC (3.3mm)</td><td>3.3</td></tr>
<tr><td>RC (4.1mm/4.8mm)</td><td>4.1/4.8</td></tr>
<tr><td rowspan="6">Dentsply Sirona Implants</td><td rowspan="2">Osseospeed</td><td>3.5/4.0</td><td>3.5 S / 4.0 S</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0/5.0 S</td></tr>
<tr><td rowspan="4">Xive</td><td>3.4</td><td>3.4</td></tr>
<tr><td>3.8</td><td>3.8</td></tr>
<tr><td>4.5</td><td>4.5</td></tr>
<tr><td>5.5</td><td>5.5</td></tr>
</table>

Table 6.1: Indications for Use (continued)

Modified Device **Sirona Dental CAD/CAM System**				**Predicate Device** **Sirona Dental CAD/CAM System (K111421)**
Indications for Use (continued)				
Manufacturer	**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	
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	

Table 6.1: Indications for Use (continued)

Modified Device **Sirona Dental CAD/CAM System**				**Predicate Device** **Sirona Dental CAD/CAM System (K111421)**
Indications for Use (continued)				
Manufacturer	**Implant System**	**Implant Size**		
		Platform	**Diameter**	
Thommen Medical	SPI ELEMENT, SPI ELEMENT INICELL, SPI CONTACT INICELL	3.5	3.5	
		4	4	
		4.5	4.5	
		5	5	
		6	6	
Osstem/Hiossen	Osstem TS Hiossen	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	

Table 6.2: Design

Modified Device **Sirona Dental CAD/CAM System**	**Primary Predicate Device** **Sirona Dental CAD/CAM System** **(K111421)**
CAD/CAM Software Version	
CEREC SW version 4.6.1	CEREC SW version 4.0
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: 3.3 mm – 6.0 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

7. Non-Clinical Performance Data

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

Tests included in this premarket notification:

- Testing to verify the conformity of the modified Sirona Dental CAD/CAM System with the requirements of IEC 60601-1: (*Medical electrical equipment Part 1: General requirements for basic safety and essential performance*).
- Testing to verify the conformity of the proposed Sirona Dental CAD/CAM System with the requirements of IEC 60601-1-2: (*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility*).

- Validation of the device's software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*) and with deliverables compiled and included with reference to *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions of Software Contained in Medical Devices* (May, 2005).

- Dynamic fatigue testing of new TiBase variants in worst-case construct according to ISO 14801 (*Dentistry - Implants - Dynamic loading test for endosseous dental implants*).

- Compatibility analyses of new TiBase interface geometries with original manufacturer's implant connection geometries. Compatibility analysis consisted of reverse engineering on OEM implant body, OEM implant abutment, and OEM implant screw, or by manufacturing agreement.

- System validation testing conducted to confirm the design and fabrication workflow of the "chairside" CAD/CAM software, CEREC SW version 4.6.1, with the defined scanning, acquisition, and milling equipment.

- New TiBase variants are composed of the identical materials and are fabricated utilizing the same methods as the components cleared under K111421. Therefore, no new biocompatibility data is included to support the substantial equivalence of the modified Sirona Dental CAD/CAM System.

- Recommended parameters for the steam sterilization of the subject TiBase components have been validated according to EN 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 (*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*).

- The subject TiBase components are provided non-sterile, to be sterilized by the end user. They are composed of the identical titanium alloy material and are provided in the same packaging configuration as the predicate TiBase components cleared under K11142. No shelf life testing was included to support substantial equivalence.

Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the "chairside" CAD/CAM software, CEREC SW version 4.6.1. Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the mesostructure component outside of design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

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.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the modified Sirona Dental CAD/CAM System. 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 K111421. The modified device also has similar indications for use and incorporates the same fundamental technology as the predicate device (K111421).

Performance and software validation data are included in this premarket notification to demonstrate the performance of the modified Sirona Dental CAD/CAM System against its design, functional, and safety requirements. The results of the testing included in this premarket notification support a determination of substantial equivalence.