August 19, 2020

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

Re: K200191
Trade/Device Name: Sirona Dental CAD/CAM System with InLab Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: July 24, 2020
Received: July 27, 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)*

K200191

Device Name

Sirona Dental CAD/CAM System with InLab Software

Indications for Use *(Describe)*

The Sirona Dental CAD/CAM System with InLab 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 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

510(k) SUMMARY
K200191
Sirona Dental CAD/CAM System
with InLab Software

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

Date Prepared: 7-August-2020

2. Device Name:

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

3. Predicate Devices:

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

Predicate Devices	**510(k)**	**Company Name**
Sirona Dental CAD/CAM System	K181520	Dentsply Sirona

Reference Devices:

Reference Device	Manufacturer	510(k) Clearance
Sirona Dental CAD/CAM System	Sirona Dental Systems GmbH	K111421
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.	K153645
CONELOG® Titanium base CAD/CAM	Altatec GmbH	K143337
iSy® Implant System	Altatect GmbH	K133991

4. Description of Device:

The Sirona Dental CAD/CAM System with InLab Software 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 functionality for the control of critical CAD/CAM abutment dimensions.

Since its original clearance in February, 2012, under K11142, the Sirona Dental CAD/CAM System has been split into two variants: the "chairside" variant, utilizing the CEREC "chairside" software, which was cleared in October, 2018, under K181520, and the "labside" variant, utilizing the InLab software and subject to this premarket notification.

Under K181520, the predicate Sirona Dental CAD/CAM System with CEREC Software was cleared for the same functionality and abutment software design limitation controls as are the subject of this premarket notification and implemented in the subject Sirona Dental CAD/CAM System with InLab Software variant.

The subject Sirona Dental CAD/CAM System with InLab Software consists of:

- InLab SW version 18.5, "labside" CAD/CAM software
- InEos X5 3D digital desktop scanner.
- InEos Blue 3D digital desktop scanner.
- InLab MC X5 milling unit.
- InLab MCXL milling unit.
- Sirona TiBase titanium base components.
- inCoris ZI zirconium mesostructure blocks.

As subject to this premarket notification, the Sirona Dental CAD/CAM System with InLab Software is utilized to digitally acquire and/or 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 and the zirconium ceramic mesostructure component which is designed using the InLab software and milled using the InLab milling equipment.

The subject InLab CAD/CAM software is to acquire the digital dental scans and to design the mesostructure component of the CAD/CAM abutments. Following the completion of the design, the subject InLab software drives the CAM fabrication of the mesostructure component in the "labside" workflow by utilizing the InLab 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 with InLab 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 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 subject Sirona Dental CAD/CAM System with InLab Software has the same intended use as the predicate Sirona Dental CAD/CAM System cleared under premarket notification K181520. Both the subject Sirona Dental CAD/CAM System with InLab Software and the predicate device (K181520) are intended for the 3D digital acquisition of the dental topography for use in the design and manufacturing of two-piece "CAD/CAM" dental abutments. As such, the subject Sirona Dental CAD/CAM System with InLab Software and the predicate device cleared under premarket notification K181520 are regulated under 21 CFR 872.3630.

The proposed indications for use of the Sirona Dental CAD/CAM System with InLab Software as subject to this premarket notification are identical to the indication for use of the predicate Sirona Dental CAD/CAM System "chairside" variant as cleared under K181520.

The subject Sirona Dental CAD/CAM System with InLab Software and the predicate Sirona Dental CAD/CAM System cleared under premarket notification K181520 utilize the same TiBase and inCoris ZI zirconia mesostructure materials for the design and fabrication of two-piece, CAD/CAM dental abutments. There are no new TiBase variants introduced in this premarket notification which were not previously cleared under the scope of K181520.

Software controls governing the limitations of critical CAD/CAM abutment design parameters, which were implemented and cleared in the predicate "chairside" variant of the Sirona Dental CAD/CAM System under K181520 are also implemented in the Sirona Dental CAD/CAM System with InLab Software as subject to this premarket notification.

The primary differences between the subject Sirona Dental CAD/CAM System with InLab Software and the predicate Sirona Dental CAD/CAM System cleared under K181520 are the acquisition scanning components and milling equipment models which are utilized for the two CAD/CAM system variants. The subject InLab system incorporates InEos X5 and InEos Blue digital desktop scanning equipment for acquisition of the dental scans, while the predicate "chairside" CAD/CAM System variant cleared under K181520 incorporates the CEREC digital acquisition and intra-oral scanning equipment.

Additionally, the subject Sirona Dental CAD/CAM System with InLab Software and the predicate Sirona Dental CAD/CAM System "chairside" variant cleared in K181520 differ with respect to the CAM milling equipment that is utilized in their respective workflows. The subject InLab system utilizes the InLab MCX5 and InLab MCXL milling units, while the predicate "chairside" system (K181520) utilizes the CEREC MCXL family of milling units.

However, the purpose of the introduction of the Sirona Dental CAD/CAM System reference device (K111421) in support of substantial equivalence is that both the "labside" and "chairside" systems were included under the scope of clearance of K111421 and this clearance was inclusive of the full range of digital scanning acquisition equipment and CAM milling equipment for both the "chairside" and InLab variants, including the InEos X5 and InEos Blue digital scanners, as well as the InLab MCX5 and MCXL milling units which are utilized in the "labside" workflow subject to this premarket notification.

Summary comparison of the intended use, indications for use, and design of the subject Sirona Dental CAD/CAM System with InLab Software and the predicate Sirona Dental CAD/CAM System cleared under K181520 is presented in Tables 6.1 and 6.2.

Table 6.1: Indications for Use

Subject Device **Sirona Dental CAD/CAM System with InLab Software**	**Predicate Device** **Sirona Dental CAD/CAM System (K181520)**
Indications for Use	
The Sirona Dental CAD/CAM System with InLab 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 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 or 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:	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	**Implant System**	**Implant Size**		**Manufacturer**	**Implant System**	**Implant Size**	
		Platform	**Diameter**			**Platform**	**Diameter**
N**ob**el Biocare	Replace	NP	3.5	N**ob**el Biocare	Replace	NP	3.5
		RP	4.3			RP	4.3
		WP	5.0			WP	5.0
		6.0	6.0			6.0	6.0
	Active	NP	3.5		Active	NP	3.5
		RP	4.3/5.0			RP	4.3/5.0
	Branemark	NP	3.3		Branemark	NP	3.3
		RP	3.75/4.0			RP	3.75/4.0
Straumann	Synocta	NN (3.5mm)	3.3	Straumann	Synocta	NN (3.5mm)	3.3
		RN (4.8mm)	3.3/4.1/4.8			RN (4.8mm)	3.3/4.1/4.8
		WN (6.5mm)	4.8			WN (6.5mm)	4.8
	Bone Level	NC (3.3mm)	3.3		Bone Level	NC (3.3mm)	3.3
		RC (4.1mm/4.8mm)	4.1/4.8			RC (4.1mm/4.8mm)	4.1/4.8
Dentsply Sirona Implants	Osseospeed	3.5/4.0	3.5 S / 4.0 S	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			4.5/5.0	4.5/5.0/5.0 S
	Xive	3.4	3.4		Xive	3.4	3.4
		3.8	3.8			3.8	3.8
		4.5	4.5			4.5	4.5
		5.5	5.5			5.5	5.5

Table 6.1: Indications for Use (continued)

Subject Device **Sirona Dental CAD/CAM System with InLab Software**				**Predicate Device** **Sirona Dental CAD/CAM System (K1181520)**			
Indications for Use (continued)							
Manufacturer	**Implant System**	**Implant Size**		**Manufacturer**	**Implant System**	**Implant Size**	
		Platform	**Diameter**			**Platform**	**Diameter**
Dentsply Sirona Implants	Osseospeed EV	3.6	3.6	Dentsply Sirona Implants	Osseospeed EV	3.6	3.6
		4.2	4.2			4.2	4.2
		4.8	4.8			4.8	4.8
		5.4	5.4			5.4	5.4
	Ankylos	C/X	A,B,C,D		Ankylos	C/X	A,B,C,D
Biomet 3i	Osseotite	3.4	3.25	Biomet 3i	Osseotite	3.4	3.25
		4.1	3.75			4.1	3.75
			4.1				4.1
			3/4				3/4
		5.0	5.0			5.0	5.0
			4/5				4/5
	Certain	3.4	3.25		Certain	3.4	3.25
			4/3				4/3
			3/4/3				3/4/3
		4.1	4.0			4.1	4.0
			4/5/4				4/5/4
			5/4				5/4
		5.0	5.0			5.0	5.0
			4/5				4/5
Zimmer	Tapered Screw Vent	3.5	3.7/4.1	Zimmer	Tapered Screw Vent	3.5	3.7/4.1
		4.5	4.7			4.5	4.7
		5.7	6			5.7	6

Table 6.1: Indications for Use (continued)

Subject Device **Sirona Dental CAD/CAM System with InLab Software**				**Predicate Device** **Sirona Dental CAD/CAM System (K181520)**			
Indications for Use (continued)							
Manufacturer	**Implant System**	**Implant Size**		**Manufacturer**	**Implant System**	**Implant Size**	
		Platform	**Diameter**			**Platform**	**Diameter**
Thommen Medical	SPI ELEMENT, SPI ELEMENT INICELL, SPI CONTACT INICELL	3.5	3.5	Thommen Medical	SPI ELEMENT, SPI ELEMENT INICELL, SPI CONTACT INICELL	3.5	3.5
		4	4			4	4
		4.5	4.5			4.5	4.5
		5	5			5	5
		6	6			6	6
Osstem/Hiossen	Osstem TS Hiossen	Mini	3.5	Osstem/Hiossen	Osstem TS Hiossen	Mini	3.5
		Regular	4.0/4.5/5.0/6.0/7.0			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	BioHorizons (Internal Connection)	Tapered 3.0,Tapered plus	3.0	3.0/3.4/3.8
	Tapered internal		3.0		Tapered internal		3.0
	Tapered plus	3.5	4.6		Tapered plus	3.5	4.6
	Tapered internal, Tapered internal tissue level		3.0/3.8		Tapered internal, Tapered internal tissue level		3.0/3.8
	Internal dental implant		3.5		Internal dental implant		3.5
	Single stage dental implants		3.5/4.0		Single stage dental implants		3.5/4.0
	Tapered Plus	4.5	5.8		Tapered Plus	4.5	5.8
	Tapered internal, Tapered internal tissue level		4.6		Tapered internal, Tapered internal tissue level		4.6
	Internal dental implant		4.0		Internal dental implant		4.0
	Single stage dental implants		4.0/5.0		Single stage dental implants		4.0/5.0
	Tapered internal, Tapered internal tissue level	5.7	5.8		Tapered internal, Tapered internal tissue level	5.7	5.8
	Internal dental implant, Single stage dental implants		5.0/6.0		Internal dental implant, Single stage dental implants		5.0/6.0

Table 6.2: Design

Subject Device **Sirona Dental CAD/CAM System with InLab Software**	**Primary Predicate Device** **Sirona Dental CAD/CAM System (K181520)**
CAD/CAM Software Version	
InLab Software version 18.5	CEREC SW version 4.6.1
Acquisition Units	
InEos X5 digital desktop scanner	CEREC AC
InEos Blue digital desktop scanner	CEREC AC Connect
	CEREC Omnicam 3D digital intraoral scanner
Milling Unit	
InLab MC X5	CEREC MC
InLab MCXL	CEREC MC X
	CEREC MC XL
	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

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).
- No new designs of TiBase variants or implant interface compatibility are proposed as subject to this premarket notification. Therefore, no new implant interface geometric compatibility analyses are included in support of substantial in this premarket notification.
- System validation testing conducted to confirm the design and fabrication workflow of the subject InLab CAD/CAM software, with the defined scanning, acquisition, and milling equipment.
- No new TiBase variants and no new materials have been introduced as subject to this premarket notification as compared to the scope of the clearance of the predicate device under K181520. Therefore, no new biocompatibility data is included to support the substantial equivalence of the subject Sirona Dental CAD/CAM System with InLab Software.
- The recommended steam sterilization parameters for the steam sterilization of the TiBase components which are compatible with the subject Sirona Dental CAD/CAM System with InLab Software are based on leveraged sterilization validation information from the predicate device cleared under premarket notification K181520.

Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the subject InLab CAD/CAM software. Software verification and validation testing was conducted to demonstrate that the software's design 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 subject Sirona Dental CAD/CAM System with InLab Software.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the subject Sirona Dental CAD/CAM System with InLab Software. The 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 subject device also has the same indications for use and incorporates the same fundamental technology as the predicate device (K181520).

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