K111421

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510(k) Summary

for

Sirona Dental Systems

Sirona Dental CAD/CAM System

1 Sponsor

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2 Device Name

Proprietary Name:	Sirona Dental CAD/CAM-System
Common/Usual Name:	Abutment, implant, dental, endosseous
Classification Names:	Endosseous dental implant abutment

3 Predicate Devices

Replace® NP, K091756, Brånemark®, K091756, Tissue level NN, K081005, OsseoSpeed™, K081666, Frialit® / Xive®, K032158, Osseotite K072642, Tapered Screw-Vent®, K060880, Nobel Active NP, K102436, Bone Level NC, K062129, Certain®, K073345.

Sirona Dental CAD/CAM System (K100152)

4 Intended 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 titanium bases SSO 3.5 L and SBL 3.3 L, the indication is restricted for 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 implants systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088, K062129, K060958)
- Biomet 3i Certain (K014235, K061629)
- Nobel Biocare Active (K071370)

5 Device Description

The Sirona Dental CAD/CAM-System takes optical impressions and records the topographical characteristics of teeth, dental impressions, or stone models. Dental restorative prosthetic devices are manufactured using computer aided design and fabrication. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments.

The system that features the processing of mesostructures comprises

- Titanium bases TiBase and Camlog

- inCoris ZI meso blocks
- Sirona Dental CAD/CAM Design and fabricating devices

Titanium bases are used as an implant prosthetic titanium base for adhesion to mesostructures to restore function and aesthetics in the oral cavity.

inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.

Sirona Dental CAD/CAM design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. This component consists of the devices CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL.

5.1 TiBase

5.1.1 Device Function

The Sirona TiBase is a premanufactured prosthetic component directly connected to dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

The Sirona offering consists of the titanium base TiBase, the abutment screw and the scanbody. The parts are marketed non-sterile and for single use only.

The Sirona TiBase is bonded to an individually designed mesostructure, a ceramic prosthetic/restoration, that supports the final restoration. The mesostructure is milled from an inCoris ZI meso block with Sirona CAD/CAM milling machines CEREC or inLab, and sintered afterwards.

The two piece abutment is mounted onto the implant and fixed with a screw.

The scope of delivery contains a scanbody (ABS plastic) which is mounted on a TiBase in order to acquire the topographical surface of the area where the endosseous dental implant abutment is located with Sirona Dental CAD/CAM fabricating devices. From the acquired data the position of the implant can be calculated. After an optical impression has been taken the scanbody is removed.

Sirona TiBase devices are compatible with following systems (Table 1):

Table 1: Sirona TiBase Devices Compatibility

Sirona TiBase	Compatible System		
	Manufacturer	**System**	**Diameter**
NBRS 3.5	Nobel Biocare	Replace® NP	3,5 mm
NBRS 4.3		Replace® RP	4.3 mm
NBRS 5.0		Replace® WP	5.0 mm
NBRS 6.0		Replace® 6.0	6.0 mm
NBB 3.4	Nobel Biocare	Brånemark®	3.4 mm
NBB 4.1		Brånemark®	4.1 mm
SSO 3.5	Straumann	Tissue level NN	3.5 mm
SSO 4.8		Tissue level RN	4.8 mm
SSO 6.5		Tissue level WN	6.5 mm
ATOS 3.5/4.0	Astra Tech	OsseoSpeed™	3.5 S / 4.0 S mm
ATOS 4.5/5.0		OsseoSpeed™	4.5 / 5.0 mm
FX 3.4	Friadent	Frialit® / Xive®	3.4 mm
FX 3.8		Frialit® / Xive®	3.8 mm
FX 4.5		Frialit® / Xive®	4.5 mm
FX 5.5		Frialit® / Xive®	5.5 mm
BO 3.4	Biomet 3i	Osseotite (Connec-tion type: Ex. Hex)	3.4 mm
BO 4.1		Osseotite (Connec-tion type: Ex. Hex)	4.1 mm

Sirona TiBase	Compatible System		
	Manufacturer	System	Diameter
BO 5.0		Osseotite (Connec-tion type: Ex. Hex)	5.0 mm
ZTSV 3.5	Zimmer	Tapered Screw-Vent®	3.5 mm
ZTSV 4.5		Tapered Screw-Vent®	4.5 mm
ZTSV 5.7		Tapered Screw-Vent®	5.7 mm
NB A 4.5	Nobel Biocare	Nobel Active NP	3.5mm
NB A 5.0		Nobel Active NP	4.3 / 5.0mm
S BL 3.3	Straumann®	Bone Level NC	3.3mm
S BL 4.1		Bone Level NC	4.1 / 4.8mm
B C 3.4	Biomet 3i	Certain®	3.4mm
B C 4.1		Certain®	4.1mm
B C 5.0		Certain®	5.0mm

5.1.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics.

5.1.3 Physical and Performance Characteristics

5.1.3.1 Design

The TiBase devices have various diameters, are compatible with dedicated implant systems, and fit to compatible implants as provided in Table 2.

Table 2: Implant Compatibility

TiBase	Implant-Manufacturer	Implant-System	510(k) Implant
NBRS	Nobel Biocare	Replace	K020646
NBB	Nobel Biocare	Branemark	K022562
FX	Friadent	Xive	K013867
BO	Biomet 3i	Osseotite	K980549
ATOS	Astra Tech	OsseoSpeed	K091239
ZTSV	Zimmer	Tapered Screw-Vent	K061410
SSO	Straumann	SynOcta	K061176
NB A	Nobel Biocare	Nobel Active	K071370
S BL	Straumann®	Bone Level	K053088
B C	Biomet 3i	Certain®	K014235

5.1.3.2 Material Used

TiBase and abutment screw are made of Ti6Al4V.

5.1.3.3 Physical Properties

TiBase material composition and mechanical properties comply with ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

Sirona TiBase devices are compatible with systems listed in Table 1.

5.2 inCoris ZI meso

5.2.1 Device Description

The inCoris ZI meso offerings are blocks of various sizes from which individual dental mesostructures are grinded by milling machines (inLab MCXL, CEREC MCXL). The mesostructure is a part of a 2 part endosseous dental implant

abutment which comprises a titanium base and a zirconium oxide mesostructure. The connection geometries are prefabricated.

5.2.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics.

5.2.3 Physical and Performance Characteristics

5.2.3.1 Design

The inCoris ZI meso are blocks of various sizes. The marketed ceramic is pre-sintered. One side of a block is mounted to a mandrel that will be inserted in the spindle's clamping chuck of the grinding machine. The connection geometry to titanium bases is prefabricated, i.e. already included in the shipped block. Connection geometries fit on Camlog (type K2244.xxxx) and Sirona (Tibase) titanium bases (Table 3 and Table 4).

Table 3: Sirona inCoris ZI meso - TiBase Devices Compatibility

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
NBRS 3.5	6282474	3,5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 4.3	6282482	4.3 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 5.0	6282490	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 6.0	6282508	6.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBB 3.4	6282516	3.4 mm	inCoris ZI	62 31 810	F0.5

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
			meso L	62 31 836	F2
NBB 4.1	6282524	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 3.5	6284231	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 4.8	6284249	4.8 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 6.5	6284256	6.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 3.5/4.0	6282532	3.5 S / 4.0 S mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 4.5/5.0	6282540	4.5 / 5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 3.4	6282433	3.4 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 3.8	6282441	3.8 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 4.5	6282458	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 5.5	6282466	5.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 3.4	6282557	3.4 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
BO 4.1	6282565	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 5.0	6282573	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 3.5	6282581	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 4.5	6282599	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 5.7	6282607	5.7 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 4.5	6308188	3.5mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 5.0	6308253	4.3 / 5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 3.3	6308154	3.3mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 4.1	6308337	4.1 / 4.8mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
B C 3.4	6308048	3.4mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
B C 4.1	6308097	4.1mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
B C 5.0	6308121	5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Table 4: Sirona inCoris ZI meso - Camlog Devices Compatibility

Titanium Base			Ceramic Block		
Camlog	**REF**	**Dia-meter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
K2244.3348	K2244.3348	3.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.3848	K2244.3848	3.8	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.4348	K2244.4348	4.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.5048	K2244.5048	5.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
K2244.6048	K2244.6048	6.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

5.2.3.2 Material Used

The inCoris ZI meso are pre-sintered zirconium oxide ceramic blocks. The metal block holder is made of aluminum. The material is composed of:

$ZrO_2+HfO_2+Y_2O_3$	> 99.0%
Al_2O_3	< 0.5%
Other oxides	< 0.5%

5.2.3.3 Physical Properties

The final technical data of inCoris ZI meso are (after final sintering):

Density:	6.06 g/cm^3
Coefficient of thermal expansion (CTE):	11.0*10-6 K^{-1}
Flexural strength:	> 900 MPa
Fracture toughness (KIC):	5.9 MPa·m$^{1/2}$

5.3 Sirona Dental CAD/CAM Design and fabrication Devices

5.3.1 Device Description

The Sirona Dental CAD/CAM Design and fabricating devices for processing mesostructures includes

- Optical acquisition or recording of the topographical characteristics of dental impressions, or stone models using the devices Acquisition unit CEREC 3, CEREC AC, and stationary scanning system inEos Blue
- Design of mesostructures and processing the acquired or recorded data for these purposes using Sirona Dental CAD/CAM Software which runs on a CEREC 3, CEREC AC or PC. Design is performed by a dentist or dental technician
- Milling of the mesostructure using CEREC MCXL or inLab MCXL milling machines from ceramic blocks intended for dental restorations and mesostructures

The Sirona Dental CAD/CAM Design and fabricating devices also processes other dental restorations like crowns, bridge-frameworks, inlays, onlays all regulated under 21 CFR 872.3661, Optical Impression Systems for CAD/CAM, for such intended use.

5.3.2 Scientific Concept

The underlying scientific concept is the use of CAD/CAM technology for the optical acquisition of the topographical characteristics of dental impressions, and models, the design of individual mesostructures using recorded data (CAD), and eventually fabricating (milling) these designed mesostructures (CAM).

5.3.3 Physical and Performance Characteristics

5.3.3.1 Design

Acquisition unit: the device consists of a camera for acquiring optical topographical characteristics of dental impressions. The recorded data are used for the design of individual mesostructures using CAD techniques specific to the dental field.

Fabricating devices: the devices mill the individual designed mesostructures from incoris ZI meso blocks. For this purpose the chucked block and the milling tools move according to prescribed trajectories to generate the shape which is intended to be milled.

5.3.3.2 Materials Used

Not applicable.

5.3.3.3 Physical Properties

Not applicable.

6 Summary of the technological characteristics

6.1 TiBase

All proposed and predicate titanium bases and screws are made of Ti6Al4V, medical grade 5. Connection interfaces to the implants are identical for each defined diameter and connection type. Connection interfaces to dental restorations differ in that proposed devices have an additional notch.

An extensive list is provided in Table 5.

6.2 inCoris ZI meso

Proposed and predicate (K100152) device are inCoris ZI meso.

There has been no modification to inCoris ZI meso from Premarket Notification K100152. Specifically, the following aspects remain identical:

- Composition
- Material properties
- Thickness / design restrictions
- Shape and bonding surface of connection interfaces to Camlog and Sirona Tibase for Sirona inCoris ZI meso blocks
- Bonding material

InCoris ZI meso is bonded to titanium bases for supporting further dental restorations.

InCoris ZI meso material is made of zirconium oxide. The composition of inCoris complies with ISO standard 13356:1997, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)". Such compositions are classified as biocompatible by this standard.

An extensive list is provided in Table 6.

6.3 Sirona Dental CAD/CAM Design and fabrication Devices

There has been no modification to the Sirona Dental CAD/CAM Design and fabricating devices from Premarket Notification K100152. Specifically, the following aspects remain identical:

- optical impressions record topographical characteristics of teeth, dental impressions, or stone models for use in the computer aided design and fabrication of dental restorative prosthetic devices in conjunction with endosseous dental implant abutments, i.e. it is an accessory
- features the transfer of data of the optical impression to a remote milling machine via internet or exportation/importation of milling data

The software database of titanium bases has been extended to cover new additional titanium bases.

An extensive list is provided in Table 7.

Table 5: Comparison of Sirona TiBase to Predicate Devices

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
NBRS 3.5	Nobel Biocare	Replace® NP	3,5 mm	Nobel Biocare product catalog page 14. Product-No. 32376	K091756	yes	yes	Internal 3 tenons	yes	same
NBRS 4.3	Nobel Biocare	Replace® RP	4.3 mm	Product-No. 32377	K091756	yes	yes	Internal 3 te-	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
								nons		
NBRS 5.0	Nobel Biocare	Replace® WP	5.0 mm	Product-No. 32378	K091756	yes	yes	Inter-nal 3 te-nons	yes	same
NBRS 6.0	Nobel Biocare	Replace® 6.0	6.0 mm	Product-No. 32375	K091756	yes	yes	Inter-nal 3 te-nons	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
NBB 3.4	Nobel Biocare	Brånemark®	3.4 mm	Nobel Biocare product catalog page 14. Product-No. 32396	K091756	yes	yes	External Hexagonal	yes	same
NBB 4.1	Nobel Biocare	Brånemark®	4.1 mm	Product-No. 32397	K091756	yes	yes	External Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
SSO 3.5	Straumann	Tissue level NN	3.5 mm	Straumann product catalog page 51. Product-No. 048.505	K081005	yes	yes	exter-nal octa-gonal	yes	same
SSO 4.8	Straumann	Tissue level RN	4.8 mm	Product-No. 048.600 (p 55)	K081005	yes	yes	Inter-nal Octa-gonal	yes	same
SSO 6.5	Straumann	Tissue level WN	6.5 mm	Product-No. 048.606	K081005	yes	yes	Inter-	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
				(p 62)				nal Octa-gonal		
ATOS 3.5/4.0	Astra Tech	OsseoSpeed™	3.5 S / 4.0 S mm	Product-No. 24285	K081666	yes	yes	Inter-nal Hexa-gonal	yes	same
ATOS 4.5/5.0	Astra Tech	OsseoSpeed™	4.5 / 5.0 mm	Product-No. 24235	K081666	yes	yes	Inter-nal Hexa-	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
								gonal		
FX 3.4	Friadent	Frialit® / Xive®	3.4 mm	Friadent product catalog page 32. Product-No. 46-2132	K032158	yes	yes	Internal Hexagonal	yes	same
FX 3.8	Friadent	Frialit® / Xive®	3.8 mm	Product-No. 46-2142	K032158	yes	yes	Internal Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
FX 4.5	Friadent	Frialit® / Xive®	4.5 mm	Product-No. 46-2152	K032158	yes	yes	Inter-nal Hexa-gonal	yes	same
FX 5.5	Friadent	Frialit® / Xive®	5.5 mm	Product-No. 46-2162	K032158	yes	yes	Inter-nal Hexa-gonal	yes	same
BO 3.4	Biomet 3i	Osseotite (Connec-tion	3.4 mm	3i Biomet product catalog page 25.	K072642	yes	yes	Exter-nal	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
		type: Ex. Hex)		Product-No. MAP32G				Hexa-gonal		
BO 4.1	Biomet 3i	Osseotite (Connec-tion type: Ex. Hex)	4.1 mm	Product-No. APP452G	K072642	yes	yes	Exter-nal Hexa-gonal	yes	same
BO 5.0	Biomet 3i	Osseotite (Connec-tion type: Ex. Hex)	5.0 mm	Product-No. WPP552G	K072642	yes	yes	Exter-nal Hexa-gonal	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
ZTSV 3.5	Zimmer	Tapered Screw-Vent®	3.5 mm	Zimmer product catalog page 9. Product-No. ZOA342S	K060880	yes	yes	Internal Hexagonal	yes	same
ZTSV 4.5	Zimmer	Tapered Screw-Vent®	4.5 mm	Product-No. ZOA442S	K060880	yes	yes	Internal Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
ZTSV 5.7	Zimmer	Tapered Screw-Vent®	5.7 mm	Product-No. ZOA562S	K060880	yes	yes	Inter-nal Hexa-gonal	yes	same
NB A 4.5	Nobel Biocare	Nobel Active NP	3,5mm	Nobel Biocare product Catalog page 71. Product-No. 34194	K102436	yes	yes	Inter-nal Hexa-gonal	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
NB A 5.0	Nobel Biocare	Nobel Active RP	4,3 / 5,0mm	Product-No. 34198	K102436	yes	yes	Inter-nal Hexa-gonal	yes	same
S BL 3.3 ®	Straumann	Bone Level NC	3,3mm	Straumann product Catalog Product-No. 022.2102	K062129	yes	yes	Inter-nal 4 slots	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
S BL 4.1	Straumann	Bone Level RC	4,1 / 4,8mm	Product-No. 022.4102	K062129	yes	yes	Inter-nal 4 slots	yes	same
B C 3.4	Biomet 3i	Certain®	3,4mm	Biomet product Catalog page 5 Product-No. IMAP32G	K073345	yes	yes	Inter-nal. Hexa-gonal	yes	same
B C 4.1	Biomet 3i	Certain®	4,1mm	Biomet product	K073345	yes	yes	Inter-nal	yes	same

Proposed Device TiBase	Predicate Device					Abut-ment and Screw made of Ti6Al4 V	Iden-tical con-nec-tion geo-metry to abut-ments	Con-nec-tion geo-metry Type	Con-nec-tion geo-metry Anti-rota-tional fea-tures	Screw geo-metry
	Manu-facturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
				Catalog page 5 Product-No. IAPP452G				Hexa-gonal		
B C 5.0	Biomet 3i	Certain®	5,0mm	Biomet product Catalog page 5 Product-No. IWPP562G	K073345	yes	yes	Inter-nal Hexa-gonal	yes	same

Table 6: Comparison of InCoris ZI meso to Predicate Device

	InCoris ZI meso	InCoris ZI meso (K100152)
Intended use	inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.	inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.
Application	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system. Please observe the indications and contraindications of the implant.	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system. Please observe the indications and contraindications of the implant.
Contra-Indications	• Insufficient oral hygiene • Insufficient space available • Bruxism • For mesostructure-geometry with angulation correction greater than 20° to the implant axis • For mesostructure-geometry with angulation correction to the implant axis for Camlog only • For individual tooth restorations with free end saddle • For restorations with a length to implant length ratio of more than 1:1.25	• Insufficient oral hygiene • Insufficient space available • Bruxism • For restorations with angulation correction to the implant axis • For individual tooth restorations with free end saddle • For restorations with a length to implant length ratio of more than 1:1.25
Technical Data		
Block-Material Composition	• ZrO2+HfO2+Y2O3: > 99.0% • Y2O3: 5.2% • HfO2: 2%	• ZrO2+HfO2+Y2O3: > 99.0% • Y2O3: 5.2% • HfO2: 2%

	InCoris ZI meso	InCoris ZI meso (K100152)
	• Al2O3: ≤ 0.05% • Fe2O3: 0.3%	• Al2O3: ≤ 0.05% • Fe2O3: 0.3%
Density (sintered)	6.06 g/cm^3	6.06 g/cm^3
Coefficient of thermal expansion (CTE)	11.0*10^{-6} K^{-1} (20 °C - 500 °C)	11.0*10^{-6} K^{-1} (20 °C - 500 °C)
Flexural strength	> 900MPa	> 900MPa
Fracture toughness (K_{IC})	5.8 MPa·m$^{1/2}$	5.8 MPa·m$^{1/2}$
Grain Size	about 0.5 µm	about 0.5 µm
Bonding Material	Panavia F 2.0 (www.kuraray-dental.de)	Panavia F 2.0 (www.kuraray-dental.de)

Table 7: Comparison of Sirona Dental CAD/CAM Design and fabricating Devices to Predicate Devices

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
Used for	The Sirona Dental CAD/CAM-System is indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments. Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL	The Sirona Dental CAD/CAM-System is indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments. Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware
Controlling of recording process (CAI) (optical impression)	Yes	Yes
Processing the recorded	Yes	Yes

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
data (data of optical impression) (CAD)		
Export of milling data to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware
Online capability	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet
Scan Implant Interface/surface	Yes (or with mounted scanbody)	Yes (or with mounted scanbody)
Scan custom wax-up	Yes	Yes
Preparation of individual restoration ("meso-structure") to be mounted on the abutment	Yes	Yes
Bond of milled ziconia/ceramic individual meso-structure to metal abutment	Yes	Yes
Create of fitting crown to be mounted on top of meso-structure	Yes	Yes
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
Used for	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments
Controlling of measurement process (CAI)	Yes	Yes
Processing the measurement data (CAD)	Yes	Yes
Export to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware

7 Nonclinical Testing

According to FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", May 12, 2004, fatigue testing has been performed for angled abutments. A reverse-engineering analysis has demonstrated that the devices are identical with their predicates and compatible with their mating implants.

Software validation testing has been performed according to IEC 62304:2006. A warning has been added warning the user that abutments with an angle of greater than 20° are out of specification.

8 Clinical Testing

Clinical testing is not required and has not been performed.

9 Conclusion

Based on a comparison of intended use, indications, construction materials, principal of operations, features and technical data, the Sirona Dental CAD/CAM System which comprises of titanium bases TiBase, inCoris ZI meso blocks and Sirona Dental CAD/CAM Design and fabricating devices are safe and effective their intended use and perform as well as and are substantially equivalent to their Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Fritz Kolle
Sirona Dental Systems GmbH
Fabrikstrasse 31
Bensheim
Germany D-64625

FEB 17 2012

Re: K111421
Trade/Device Name: Sirona Dental CAD/CAM System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 14, 2012
Received: February 16, 2012

Dear Mr. Kolle:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Sirona Dental CAD/CAM System

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. 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:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088)
- Biomet 3i Certain (K014235)
- Nobel Biocare Active (K071370)

for Dr S. Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111421

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)