November 16, 2020

Ivoclar Vivadent, AG
% Lori Aleshin
Director of Quality & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K193193
Trade/Device Name: Telio® CAD Abutment Solutions- extra systems
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: October 1, 2020
Received: October 13, 2020

Dear Lori Aleshin:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193193

Device Name

Telio® CAD Abutment Solutions- extra systems

Indications for Use *(Describe)*

Telio CAD Abutment Solutions is intended for single hybrid abutment crowns for temporary restoration (up to 12 months).

The system comprises three parts:
- Telio CAD Abutment Solutions
- Ti base and (Dentsply Sirona K181520, Camlog K083496, Conelog K143337, iSy K133991)
- CAD/CAM software: Sirona Dental CAD/CAM System (K100152, K111521, K181520)

Telio CAD Abutment Solutions is cemented to the Ti base and used in conjunction with endosseous dental implants. The compatible implant systems, CAD/CAM systems and Ti bases are shown below:

-Implant systems:
The Telio CAD PMMA structure and TiBase hybrid abutment is compatible with the following implant systems:

– AstraTech Osseospeed (Dentsply Sirona K130999, K091239)
– Frialit/Xive (Dentsply Sirona K013867))
– internal connection (BioHorizons K143022, K071638, K093321, K042429)
– Replace (Nobel Biocare K020646)
– Nobel Active (Nobel Biocare K071370)
– Brånemark® (Nobel Biocare K022562)
– Tissue Level (Straumann K061176)
– Tapered Screw-Vent (Zimmer K061410)
– Camlog Screw-Line (Camlog K083496)
– Conelog Screw-Line (Camlog K113779)
– iSy (Camlog K133991)
– Osstem TS (Osstem (USA: Hiossen) K121585)

Dentsply Sirona TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Dentsply Sirona Ref.	Interface size
Dentsply Sirona	AstraTech Osseospeed EV 3.6	3.6	3.6	AT EV 3.6 GH1 S	6586312	S
	AstraTech Osseospeed EV 4.2	4.2	4.2	AT EV 4.2 GH1 L	6586320	L
	AstraTech Osseospeed EV 4.8	4.8	4.8	AT EV 4.8 GH1 L	6586338	
	AstraTech Osseospeed EV 5.4	5.4	5.4	AT EV 5.4 GH1 L	6586346	
	AstraTech Osseospeed TX 3.5/4.0	3.5 S/ 4.0 S	3.5 / 4.0	AT OS 3.5/4.0 L	6282532	L
	AstraTech Osseospeed TX 4.5/5.0	4.5/ 5.0/ 5.0 S	4.5 / 5.0	AT OS 4.5/5.0 L	6282540	
	Frialit/ Xive 3.4	3.4	3.4	FX 3.4 S	6282433	S
	Frialit/ Xive 3.8	3.8	3.8	FX 3.8 S	6282441	
	Frialit/ Xive 4.5	4.5	4.5	FX 4.5 L	6282458	L
	Frialit/ Xive 5.5	5.5	5.5	FX 5.5 L	6282466	
BioHorizons	internal connection 3.0	3.0 /3.8	3.0	BH 3.0 S	6532779	S
	internal connection 3.5	3.0/3.5/3.8/4.0/4.6	3.5	BH 3.5 L	6532894	L
	internal connection 4.5	4.0/ 4.6/ 5.0/ 5.8	4.5	BH 4.5 L	6532951	
	internal connection 5.7	5.0/ 5.8/ 6.0	5.7	BH 5.7 L	6536242	
Nobel Biocare	Replace NP	3.5	NP	NB RS 3.5 L	6282474	L
	Replace RP	4.3	RP	NB RS 4.3 L	6282482	
	Replace WP	5	WP	NB RS 5.0 L	6282490	
	Replace 6.0	6	6.0	NB RS 6.0 L	6282508	
	Nobel Active NP	3.5	NP	NB A 4.5 L	6308188	
	Nobel Active RP	4.3/ 5.0	RP	NB A 5.0 L	6308253	
	Brånemark® NP	3.3	NP	NB B 3.4 L	6282516	
	Brånemark® RP	3.75/ 4.0	RP	NB B 4.1 L	6282524	
Osstem (USA: Hiossen)	Osstem TS Mini	3.5	Mini	O TS 3.5 L	6527035	L
	Osstem TS Standard	4.0/4.5/5.0/6.0/7.0	Standard	O TS 4.0 L	6527043	
Straumann	Bone Level NC	3.3	NC (3.3 mm)	S BL 3.3 L	6308154	L
	Tissue Level RN	4.8	RN (4.8)	S SO 4.8 L	6284249	
	Tissue Level WN	6.5	WM (6.5)	S SO 6.5 L	6284256	
Zimmer	Tapered Screw-Vent 3.5	3.7/ 4.1	3.5	Z TSV 3.5 L	6282581	L
	Tapered Screw-Vent 4.5	4.7	4.5	Z TSV 4.5 L	6282599	
	Tapered Screw-Vent 5.7	6	5.7	Z TSV 5.7 L	6282607	

For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single laterial incisors in the maxilla and lateral and central incisors in the mandible.

Camlog TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Camlog Ref.	Interface size
Camlog	Camlog Screw-Line 3.3	3.3	3.3	CAMLOG® Titanium base CAD/CAM, for Ø 3.3 mm	K2244.3348	S
	Camlog Screw-Line 3.8	3.8	3.8	CAMLOG® Titanium base CAD/CAM, for Ø 3.8 mm	K2244.3848	
	Camlog Screw-Line 4.3	4.3	4.3	CAMLOG® Titanium base CAD/CAM, for Ø 4.3 mm	K2244.4348	
	Camlog Screw-Line 5.0	5.0	5.0	CAMLOG® Titanium base CAD/CAM, for Ø 5.0 mm	K2244.5048	L
	Camlog Screw-Line 6.0	6.0	6.0	CAMLOG® Titanium base CAD/CAM, for Ø 6.0 mm	K2244.6048	
	Conelog Screw-Line 3.3	3.3	3.3	CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 0.8 mm	C2242.3308	S
				CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 2.0 mm	C2242.3320	
	Conelog Screw-Line 3.8	3.8	3.8	CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 0.8 mm	C2242.3808	
				CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 2.0 mm	C2242.3820	
	Conelog Screw-Line 4.3	4.3	4.3	CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 0.8 mm	C2242.4308	
				CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 2.0 mm	C2242.4320	
	Conelog Screw-Line 5.0	5.0	5.0	CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 0.8 mm	C2242.5008	L
				CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 2.0 mm	C2242.5020	
	iSy 3.8 / 4.4 / 5.0	3.8/ 4.0/ 5.0	3.8/ 4.4/ 5.0	iSy® Titanium base CAD/CAM, Ø 4.5 mm, GH 0.8 mm	P2244.4408	S
				iSy® Titanium base CAD/CAM, Ø 4.5 mm, GH 2.0 mm	P2244.4420	
				iSy® Titanium base CAD/CAM, Ø 5.2 mm, GH 0.8 mm	P2244.5008	L
				iSy® Titanium base CAD/CAM, Ø 5.2 mm, GH 2.0 mm	P2244.5020	

Type of Use *(Select one or both, as applicable)*

X 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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510(K) SUMMARY

Telio® CAD Abutment Solutions- extra systems- K193193

Contact: Lori Aleshin, Director of Quality and Regulatory Affairs
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716-264-2045
lori.aleshin@ivoclarvivadent.com

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: November 16, 2020

Proprietary Name: **Telio® CAD Abutment Solutions- extra systems**

Primary Classification Name: Endosseous dental implant abutment
(21 CFR 872.3630)

Primary Product Code: NHA

Secondary Product Code: PNP

Primary Predicate Device: Telio® CAD Abutment Solutions (K151564) by Ivoclar Vivadent, AG

Reference Devices: Sirona Dental CAD/CAM System (K100152)

Sirona Dental CAD/CAM System (K111421)

Sirona Dental CAD/CAM System (K181520)

Device Description: The **Telio® CAD Abutment Solutions- extra systems** which is the subject of this premarket notification is a modification to the Telio Abutment Solutions as previously cleared under K151564. The modifications represented in the subject device consist of the addition of 14 extra implant systems to the 2 previously cleared implant systems. The device Telio CAD (K093708) is currently cleared by the FDA as a Crown and Bridge, Temporary Resin (21 C.F.R§872.3770) because it is a device that offers a rapid route to effective temporary restorations. The currently cleared Telio CAD Abutment Solutions (K151564) included the system Straumann Bone Level, but not all the parts of this system (i.e. NC) were mentioned. This submission includes 14 additional systems.

Telio CAD Abutment Solutions- extra systems is intended for use in single hybrid abutment crowns for temporary restoration (up to 12 months). Telio CAD Abutment Solutions is a system comprising of three parts: Telio CAD Abutment Solution, cross-linked polymer block (PMMA), enabling the fabrication of individual, monolithic hybrid abutment crowns which are directly cemented to a Ti base, utilizing Sirona CAD/CAM System to design and fabricate long term temporaries by means of the CAD/CAM technique. The abutments being two-piece

titanium base abutments are mated with a PMMA top-half, in which the assembly comprises the final-finished medical device of a patient-specific dental abutment.

For the fabrication of Telio CAD Abutment Solutions, the clinical situation is digitalized either by a direct intraoral scan or an indirect model scan, depending on the CAD/CAM system used. For notes regarding the scan, please observe the manufacturer's instructions for use of the CAD/CAM system.

Compatible Systems:
Dentsply Sirona CEREC® and inLab®
Updated material and TiBase library datasets relating to Dentsply Sirona's Sirona Dental CAD/CAM System with CEREC SW chairside software are obtained by download at:
https://my.cerec.com

For detailed information regarding the use of Dentsply Sirona's Sirona Dental CAD/CAM System with CEREC SW chairside software, please refer to the CAD/CAM system's operator's manual provided by Dentsply Sirona.

Existing Implant Systems (K151564)
Bone Level RC
Certain

Extra Implant Systems
AstraTech Osseospeed EV 3.6
AstraTech Osseospeed EV 4.2
AstraTech Osseospeed EV 4.8
AstraTech Osseospeed EV 5.4
AstraTech Osseospeed TX 3.5/4.0
AstraTech Osseospeed TX 4.5/5.0
Frialit/ Xive 3.4
Frialit/ Xive 3.8
Frialit/ Xive 4.5
Frialit/ Xive 5.5
internal connection 3.0
internal connection 3.5
internal connection 4.5
internal connection 5.7
Replace NP
Replace RP
Replace WP
Replace 6.0
Nobel Active NP
Nobel Active RP
Brånemark® NP
Brånemark® RP
Osstem TS Mini
Osstem TS Standard
Bone Level NC
Tissue Level RN
Tissue Level WN
Tapered Screw-Vent 3.5
Tapered Screw-Vent 4.5
Tapered Screw-Vent 5.7

Camlog Screw-Line
Conelog Screw-Line
iSy

Predicate Device: The primary predicate devices to which Telio® CAD Abutment Solutions- extra systems has been compared is Ivoclar Vivadent, AG Telio® CAD Abutment Solutions (K151564).

For this application, Telio® CAD Abutment Solutions- extra systems has been compared to its predicate and found equivalent with regard to the contraindications, biocompatibility, storage, technology and device specification, classification, and storage. The comparison shows that

Telio® CAD Abutment Solutions- extra systems is substantially equivalent to the predicate device.

The indications and working principle only differ in the fact, that Telio CAD Abutment Solutions can now be used with 14 extra systems in addition to the predicate devices 2 implant systems (i.e., Bone Level RC and Certain).

The fatigue testing performed for the listed extra systems proves that Telio CAD Abutment Solutions can be used with the 14 additional implant systems.

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
Manufacturer	Ivoclar Vivadent, AG	Ivoclar Vivadent, AG	Dentsply Sirona		
Indications for Use: **Telio CAD Abutment Solutions- extra systems (K193193)**	Telio CAD Abutment Solutions is intended for single hybrid abutment crowns for temporary restoration (up to 12 months). The system comprises three parts: - Telio CAD Abutment Solutions - Ti base and (Dentsply Sirona K181520, Camlog K083496, Conelog K143337, iSy K133991) - CAD/CAM software: Sirona Dental CAD/CAM System (K100152, K111521, K181520) Telio CAD Abutment Solutions is cemented to the Ti base and used in conjunction with endosseous dental implants. The compatible implant systems, CAD/CAM systems and Ti bases are shown below: -Implant systems: The Telio CAD PMMA structure and TiBase hybrid abutment is compatible with the following implant systems: – AstraTech Osseospeed (Dentsply Sirona K130999, K091239) – Frialit/Xive (Dentsply Sirona K013867)) – internal connection (BioHorizons K143022, K071638, K093321, K042429) – Replace (Nobel Biocare K020646) – Nobel Active (Nobel Biocare K071370) – Bränemark® (Nobel Biocare K022562) – Tissue Level (Straumann K061176)				

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
	– Tapered Screw-Vent (Zimmer K061410) – Camlog Screw-Line (Camlog K083496) – Conelog Screw-Line (Camlog K113779) – iSy (Camlog K133991) – Osstem TS (Osstem (USA: Hiossen) K121585)				

Dentsply Sirona TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Dentsply Sirona Ref.	Interface size
Dentsply Sirona	AstraTech Osseospeed EV 3.6	3.6	3.6	AT EV 3.6 GH1 S	6586312	S
	AstraTech Osseospeed EV 4.2	4.2	4.2	AT EV 4.2 GH1 L	6586320	L
	AstraTech Osseospeed EV 4.8	4.8	4.8	AT EV 4.8 GH1 L	6586338	
	AstraTech Osseospeed EV 5.4	5.4	5.4	AT EV 5.4 GH1 L	6586346	
	AstraTech Osseospeed TX 3.5/4.0	3.5 S/ 4.0 S	3.5 / 4.0	AT OS 3.5/4.0 L	6282532	L
	AstraTech Osseospeed TX 4.5/5.0	4.5/ 5.0/ 5.0 S	4.5 / 5.0	AT OS 4.5/5.0 L	6282540	
	Frialit/ Xive 3.4	3.4	3.4	FX 3.4 S	6282433	S
	Frialit/ Xive 3.8	3.8	3.8	FX 3.8 S	6282441	
	Frialit/ Xive 4.5	4.5	4.5	FX 4.5 L	6282458	L
	Frialit/ Xive 5.5	5.5	5.5	FX 5.5 L	6282466	
BioHorizons	internal connection 3.0	3.0 /3.8	3.0	BH 3.0 S	6532779	S
	internal connection 3.5	3.0/3.5/3.8/4.0/4.6	3.5	BH 3.5 L	6532894	L
	internal connection 4.5	4.0/ 4.6/ 5.0/ 5.8	4.5	BH 4.5 L	6532951	
	internal connection 5.7	5.0/ 5.8/ 6.0	5.7	BH 5.7 L	6536242	
Nobel Biocare	Replace NP	3.5	NP	NB RS 3.5 L	6282474	L
	Replace RP	4.3	RP	NB RS 4.3 L	6282482	
	Replace WP	5	WP	NB RS 5.0 L	6282490	
	Replace 6.0	6	6.0	NB RS 6.0 L	6282508	
	Nobel Active NP	3.5	NP	NB A 4.5 L	6308188	
	Nobel Active RP	4.3/ 5.0	RP	NB A 5.0 L	6308253	
	Brånemark® NP	3.3	NP	NB B 3.4 L	6282516	
	Brånemark® RP	3.75/ 4.0	RP	NB B 4.1 L	6282524	
Osstem (USA: Hiossen)	Osstem TS Mini	3.5	Mini	O TS 3.5 L	6527035	L
	Osstem TS Standard	4.0/4.5/5.0/6.0/7.0	Standard	O TS 4.0 L	6527043	
Straumann	Bone Level NC	3.3	NC (3.3 mm)	S BL 3.3 L	6308154	L
	Tissue Level RN	4.8	RN (4.8)	S SO 4.8 L	6284249	
	Tissue Level WN	6.5	WM (6.5)	S SO 6.5 L	6284256	
Zimmer	Tapered Screw-Vent 3.5	3.7/ 4.1	3.5	Z TSV 3.5 L	6282581	L
	Tapered Screw-Vent 4.5	4.7	4.5	Z TSV 4.5 L	6282599	
	Tapered Screw-Vent 5.7	6	5.7	Z TSV 5.7 L	6282607	

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
	For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.				

ivoclar vivadent
passion vision innovation

Camlog TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Camlog Ref.	Interface size
Camlog	Camlog Screw-Line 3.3	3.3	3.3	CAMLOG® Titanium base CAD/CAM, for Ø 3.3 mm	K2244.3348	S
	Camlog Screw-Line 3.8	3.8	3.8	CAMLOG® Titanium base CAD/CAM, for Ø 3.8 mm	K2244.3848	
	Camlog Screw-Line 4.3	4.3	4.3	CAMLOG® Titanium base CAD/CAM, for Ø 4.3 mm	K2244.4348	
	Camlog Screw-Line 5.0	5.0	5.0	CAMLOG® Titanium base CAD/CAM, for Ø 5.0 mm	K2244.5048	L
	Camlog Screw-Line 6.0	6.0	6.0	CAMLOG® Titanium base CAD/CAM, for Ø 6.0 mm	K2244.6048	
	Conelog Screw-Line 3.3	3.3	3.3	CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 0.8 mm	C2242.3308	S
				CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 2.0 mm	C2242.3320	
	Conelog Screw-Line 3.8	3.8	3.8	CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 0.8 mm	C2242.3808	
				CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 2.0 mm	C2242.3820	
	Conelog Screw-Line 4.3	4.3	4.3	CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 0.8 mm	C2242.4308	
				CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 2.0 mm	C2242.4320	
	Conelog Screw-Line 5.0	5.0	5.0	CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 0.8 mm	C2242.5008	L
				CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 2.0 mm	C2242.5020	
	iSy 3.8 / 4.4 / 5.0	3.8/ 4.0/ 5.0	3.8/ 4.4/ 5.0	iSy® Titanium base CAD/CAM, Ø 4.5 mm, GH 0.8 mm	P2244.4408	S
				iSy® Titanium base CAD/CAM, Ø 4.5 mm, GH 2.0 mm	P2244.4420	
				iSy® Titanium base CAD/CAM, Ø 5.2 mm, GH 0.8 mm	P2244.5008	L
				iSy® Titanium base CAD/CAM, Ø 5.2 mm, GH 2.0 mm	P2244.5020	

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
Indications for Use: **Telio CAD Abutment Solutions (K151564)**	Telio CAD Abutment Solutions is intended for single hybrid abutment crowns for temporary restoration (up to 12 months). The system comprises three parts: - Telio CAD Abutment Solutions - Ti base and - CAD/CAM software Telio CAD Abutment Solutions is cemented to the Ti base and used in conjunction with endosseous dental implants. The compatible implant systems, CAD/CAM systems and Ti bases are shown below: -Implant systems: Straumann Bone Level (K053088), Biomet 3 Certain (K014235) -CAD/CAM Systems: Sirona inLab and Cerec SW 4.2 and above (K100152 and K111421) - Titanium bases (K100152 and K111421):				

Implant Mfg.	Implant System	Implant Diameter (mm)	Ti Base	Sirona Ref.	Interface size
Straumann	Bone Level RC	4.1/4.8	S BL 4.1	6308337	L
Biomet 3i	Certain	3.4	BC 3.4	6308048	S
		4.1	BC 4.1	6308097	L
		5.0	BC 5.0	6308121	L

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
Indication for Use Differences:	The indications only differ in the fact, that Telio CAD Abutment Solutions now can be used with 13 additional implant systems and Straumann Bone Level NC. Fatigue testing for the listed extra systems has been performed and discussed more fully in the Performance Testing- Bench section of this application. Therefore the devices are substantially equivalent.				
Compatibility	The Telio CAD mesostructure and TiBase two-piece abutment is compatible with the following Implant Systems: -Dentsply Sirona: Astra Tech Osseospeed EV (K130999) Astra Tech Osseospeed TX (K091239) Friadent XiVE (K013867), -BioHorizons Implant System: Internal connection (K143022, K071638, K093321, K042429) -Nobel Biocare Replace (K020646), Active Internal (K071370) Branemark (K022562), -Osstem: TS Implant System (K121585)	The Telio CAD mesostructured and TiBase two-piece abutment is compatible with the following Implant Systems: - Biomet 3: Straumann Bone Level (K053088), - Biomet 3 Certain (K014235)	The InCoris mesostructured 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)	The InCoris mesostructured 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)	The InCoris mesostructured and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646) Nobel Biocare Active (K071370) Nobel Biocare Branemark (K022562) Straumann SynOcta (K061176)

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
	-Straumann Standard Tissue Level RN/WN (K061176) -Zimmer TSV (K061410) -Camlog: Camlog Screw-Line, Conelog Screw-Line, iSy (K083496, K113779, K133991)		AstraTech Osseospeed (K091239) Zimmer Tapered Screw-Vent (K061410) Straumann SynOcta (K061176)	AstraTech 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)	Straumann Bone Level (K053088, K062129, K060958) Dentsply Sirona Osseospeed (K091239) Xive (K013867) Dentsply Sirona Osseospeed EV (K130999) Dentsply Sirona Ankylos (K140347, K083805) Biomet 3i Osseotite (K980549) Biomet 3i Certain (K014235, K061629)

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
					Zimmer Tapered Screw-Vent (K061410) Thomenn Medical SPI (K093615, K090154) Osstem/Hiossen Osstem TS/ Hiossen (K121585, K140934, K101096) BioHorizons Internal Connections (K143022, K071638, K093321, K04249)
General Design	Telio CAD Abutment Solutions are polymethyl methacrylate (PMMA) blocks in various sizes. One side of the block is mounted to a mandrel that will be inserted into the spindle's clamping chuck of the grinding machine. The connection	Telio CAD Abutment Solutions are polymethyl methacrylate (PMMA) blocks in various sizes. One side of the block is mounted to a mandrel that will be inserted into the spindle's clamping chuck of the grinding machine. The connection	The Sirona TiBase is a premanufactured prosthetic component directly connected to endosseous dental implants with a screw and is intended for use as an aid in prosthetic rehabilitation.		

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
	geometry to titanium bases is prefabricated, i.e. already included in the shipped block. Telio CAD Abutment Solutions is used to prepare a patient-specific temporary restoration using CAD/CAM technology. The monolithically milled hybrid abutment crown is extraorally cemented to the Ti base by means of Multilink Hybrid Abutment HO 0. Then the restoration is screwed onto the implant in one piece. Finally, the screw channel is sealed with a composite or a light-curing temporary restorative material.	geometry to titanium bases is prefabricated, i.e. already included in the shipped block. Telio CAD Abutment Solutions is used to prepare a patient-specific temporary restoration using CAD/CAM technology. The monolithically milled hybrid abutment crown is extraorally cemented to the Ti base by means of Multilink Hybrid Abutment HO 0. Then the restoration is screwed onto the implant in one piece. Finally, the screw channel is sealed with a composite or a light-curing temporary restorative material.			
Abutment Angle	0°	0° to 20°	0° to 20°		
Restoration	Temporary Single Unit	Single Unit	Single Unit, Multi-Unit		
Block Material	Polymethyl methacrylate (PMMA)	Polymethyl methacrylate (PMMA)	InCoris	InCoris	InCoris

Technological Characteristics	Proposed Device: Telio CAD Abutment Solutions- extra systems (K193193)	Primary Predicate Device: Telio® CAD Abutment Solutions (K151564)	Reference Device: Sirona Dental CAD/CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
Cement (Adhesive)	Multilink Hybrid Abutment	Multilink Hybrid Abutment	Panavia F2.0	Panavia F2.0	Panavia F2.0
Sterilization Method	Autoclave 121°C at 30 min	Autoclave 121°C at 20 min	Steam Sterilization	Steam Sterilization	Steam Sterilization
Use	Single Use	Single Use	Single-Use	Single-Use	Single-Use

510(K) SUMMARY

Indications for Use Statement:

Telio CAD Abutment Solutions is intended for single hybrid abutment crowns for temporary restoration (up to 12 months).

The system comprises three parts:
- Telio CAD Abutment Solutions
- Ti base and (Dentsply Sirona K181520, Camlog K083496, Conelog K143337, iSy K133991)
- CAD/CAM software: Sirona Dental CAD/CAM System (K100152, K111521, K181520)

Telio CAD Abutment Solutions is cemented to the Ti base and used in conjunction with endosseous dental implants. The compatible implant systems, CAD/CAM systems and Ti bases are shown below:

-Implant systems:
The Telio CAD PMMA structure and TiBase hybrid abutment is compatible with the following implant systems:

– AstraTech Osseospeed (Dentsply Sirona K130999, K091239)
– Frialit/Xive (Dentsply Sirona K013867))
– internal connection (BioHorizons K143022, K071638, K093321, K042429)
– Replace (Nobel Biocare K020646)
– Nobel Active (Nobel Biocare K071370)
– Brånemark® (Nobel Biocare K022562)
– Tissue Level (Straumann K061176)
– Tapered Screw-Vent (Zimmer K061410)
– Camlog Screw-Line (Camlog K083496)
– Conelog Screw-Line (Camlog K113779)
– iSy (Camlog K133991)
– Osstem TS (Osstem (USA: Hiossen) K121585)

510(K) SUMMARY

Dentsply Sirona TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Dentsply Sirona Ref.	Interface size
Dentsply Sirona	AstraTech Osseospeed EV 3.6	3.6	3.6	AT EV 3.6 GH1 S	6586312	S
	AstraTech Osseospeed EV 4.2	4.2	4.2	AT EV 4.2 GH1 L	6586320	L
	AstraTech Osseospeed EV 4.8	4.8	4.8	AT EV 4.8 GH1 L	6586338	
	AstraTech Osseospeed EV 5.4	5.4	5.4	AT EV 5.4 GH1 L	6586346	
	AstraTech Osseospeed TX 3.5/4.0	3.5 S/ 4.0 S	3.5 / 4.0	AT OS 3.5/4.0 L	6282532	L
	AstraTech Osseospeed TX 4.5/5.0	4.5/ 5.0/ 5.0 S	4.5 / 5.0	AT OS 4.5/5.0 L	6282540	
	Frialit/ Xive 3.4	3.4	3.4	FX 3.4 S	6282433	S
	Frialit/ Xive 3.8	3.8	3.8	FX 3.8 S	6282441	
	Frialit/ Xive 4.5	4.5	4.5	FX 4.5 L	6282458	L
	Frialit/ Xive 5.5	5.5	5.5	FX 5.5 L	6282466	
BioHorizons	internal connection 3.0	3.0 /3.8	3.0	BH 3.0 S	6532779	S
	internal connection 3.5	3.0/3.5/3.8/4.0/4.6	3.5	BH 3.5 L	6532894	L
	internal connection 4.5	4.0/ 4.6/ 5.0/ 5.8	4.5	BH 4.5 L	6532951	
	internal connection 5.7	5.0/ 5.8/ 6.0	5.7	BH 5.7 L	6536242	
Nobel Biocare	Replace NP	3.5	NP	NB RS 3.5 L	6282474	L
	Replace RP	4.3	RP	NB RS 4.3 L	6282482	
	Replace WP	5	WP	NB RS 5.0 L	6282490	
	Replace 6.0	6	6.0	NB RS 6.0 L	6282508	
	Nobel Active NP	3.5	NP	NB A 4.5 L	6308188	
	Nobel Active RP	4.3/ 5.0	RP	NB A 5.0 L	6308253	
	Brånemark' NP	3.3	NP	NB B 3.4 L	6282516	
	Brånemark' RP	3.75/ 4.0	RP	NB B 4.1 L	6282524	
Osstem (USA: Hiossen)	Osstem TS Mini	3.5	Mini	O TS 3.5 L	6527035	L
	Osstem TS Standard	4.0/4.5/5.0/6.0/7.0	Standard	O TS 4.0 L	6527043	
Straumann	Bone Level NC	3.3	NC (3.3 mm)	S BL 3.3 L	6308154	L
	Tissue Level RN	4.8	RN (4.8)	S SO 4.8 L	6284249	
	Tissue Level WN	6.5	WM (6.5)	S SO 6.5 L	6284256	
Zimmer	Tapered Screw-Vent 3.5	3.7/ 4.1	3.5	Z TSV 3.5 L	6282581	L
	Tapered Screw-Vent 4.5	4.7	4.5	Z TSV 4.5 L	6282599	
	Tapered Screw-Vent 5.7	6	5.7	Z TSV 5.7 L	6282607	

For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single laterial incisors in the maxilla and lateral and central incisors in the mandible.

510(K) SUMMARY

Camlog TiBase

Implant manufacturer	Implant System	Implant Size Diameter (mm)	Implant Size Platform (mm)	TiBase	Camlog Ref.	Interface size
Camlog	Camlog Screw-Line 3.3	3.3	3.3	CAMLOG® Titanium base CAD/CAM, for Ø 3.3 mm	K2244.3348	S
	Camlog Screw-Line 3.8	3.8	3.8	CAMLOG® Titanium base CAD/CAM, for Ø 3.8 mm	K2244.3848	
	Camlog Screw-Line 4.3	4.3	4.3	CAMLOG® Titanium base CAD/CAM, for Ø 4.3 mm	K2244.4348	
	Camlog Screw-Line 5.0	5.0	5.0	CAMLOG® Titanium base CAD/CAM, for Ø 5.0 mm	K2244.5048	L
	Camlog Screw-Line 6.0	6.0	6.0	CAMLOG® Titanium base CAD/CAM, for Ø 6.0 mm	K2244.6048	
	Conelog Screw-Line 3.3	3.3	3.3	CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 0.8 mm	C2242.3308	S
				CONELOG® Titanium base CAD/CAM, for Ø 3.3 mm, GH 2.0 mm	C2242.3320	
	Conelog Screw-Line 3.8	3.8	3.8	CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 0.8 mm	C2242.3808	
				CONELOG® Titanium base CAD/CAM, for Ø 3.8 mm, GH 2.0 mm	C2242.3820	
	Conelog Screw-Line 4.3	4.3	4.3	CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 0.8 mm	C2242.4308	
				CONELOG® Titanium base CAD/CAM, for Ø 4.3 mm, GH 2.0 mm	C2242.4320	
	Conelog Screw-Line 5.0	5.0	5.0	CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 0.8 mm	C2242.5008	L
				CONELOG® Titanium base CAD/CAM, for Ø 5.0 mm, GH 2.0 mm	C2242.5020	
	iSy 3.8 / 4.4 / 5.0	3.8/ 4.0/ 5.0	3.8/ 4.4/ 5.0	iSy® Titanium base CAD/CAM, Ø 4.5 mm, GH 0.8 mm	P2244.4408	S
				iSy® Titanium base CAD/CAM, Ø 4.5 mm, GH 2.0 mm	P2244.4420	
				iSy® Titanium base CAD/CAM, Ø 5.2 mm, GH 0.8 mm	P2244.5008	L
				iSy® Titanium base CAD/CAM, Ø 5.2 mm, GH 2.0 mm	P2244.5020	

Dentsply Sirona`s TiBases:

All TiBases mentioned in the table manufactured by Dentsply Sirona are cleared under K181520.

Camlog titanium bases:

Product ID	Product description	510k number
K2244.3348	CAMLOG® Titanium base CAD/CAM Ø 3.3 mm	K083496
K2244.3848	CAMLOG® Titanium base CAD/CAM Ø 3.8 mm	K083496
K2244.4348	CAMLOG® Titanium base CAD/CAM Ø 4.3 mm	K083496
K2244.5048	CAMLOG® Titanium base CAD/CAM Ø 5.0 mm	K083496
K2244.6048	CAMLOG® Titanium base CAD/CAM Ø 6.0 mm	K083496
C2242.3308	CONELOG® Titanium base CAD/CAM d 3.3 mm GH 0.8 mm	K143337
C2242.3320	CONELOG® Titanium base CAD/CAM d 3.3 mm GH 2.0 mm	K143337
C2242.3808	CONELOG® Titanium base CAD/CAM d 3.8 mm GH 0.8 mm	K143337
C2242.3820	CONELOG® Titanium base CAD/CAM d 3.8 mm GH 2.0 mm	K143337
C2242.4308	CONELOG® Titanium base CAD/CAM d 4.3 mm GH 0.8 mm	K143337
C2242.4320	CONELOG® Titanium base CAD/CAM d 4.3 mm GH 2.0 mm	K143337
C2242.5008	CONELOG® Titanium base CAD/CAM d 5.0 mm GH 0.8 mm	K143337
C2242.5020	CONELOG® Titanium base CAD/CAM d 5.0 mm GH 2.0 mm	K143337
P2244.4408	iSy® Titanium base CAD/CAM d 4.5 mm - GH 0.8 mm	K133991
P2244.4420	iSy® Titanium base CAD/CAM d 4.5 mm - GH 2.0 mm	K133991
P2244.5008	iSy® Titanium base CAD/CAM d 5.2 mm - GH 0.8 mm	K133991
P2244.5020	iSy® Titanium base CAD/CAM d 5.2 mm - GH 2.0 mm	K133991

Non-clinical performance testing:

Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: Flexural Strength, Water sorption, Solubility, Flexural modulus, and Ball indentation hardness according to EN 1641:2009. The subject device was tested in direct comparison to the predicate device and the results of the bench testing show the products to be substantially equivalent.

All other applicable non-clinical testing, including sterilization validation, is leveraged from the listed predicate/reference devices.

Biocompatibility:

The subject device leveraged information previously submitted in Telio CAD Abutment Solutions (K151564) submission to show the substantially equivalent biocompatibility of the device.

Technological Characteristics:

The device design, i.e. delivery form and composition of Telio CAD Abutment Solutions- extra systems and the predicate device are the same. The indications for use of the Telio CAD Abutment Solutions have been modified relative to the expansion of implant systems to which the existing TiBase component offerings are compatible (i.e., the addition of AstraTech Osseospeed, Frialit/Xive, Internal connection, Replace, Nobel Active, Brånemark®, Bone Level NC, Tissue Level, Tapered Screw-Vent, Camlog, and Osstem TS)

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 names, implant platform size, and diameter for each of the compatible implant systems. This clarification to the compatibility list has been made for clear identification of compatible implant systems.

Testing Summary:

The device was designed and tested in accordance with guidance document for Root Form Endosseous Dental Implants and Abutments, May 12, 2004 and with ISO 14801:2007 Dentistry – Implants – Dynamic fatigue test for endosseous dental implants. This standard is recognized by the FDA under Recognition Number 4-195. All other applicable non-clinical testing is leveraged from the listed predicate/reference devices.

Conclusion:

Telio CAD Abutment Solutions- extra systems is substantially equivalent to the predicate device.