August 26, 2019

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

Re: K191382
Trade/Device Name: IPS e.max® 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: July 22, 2019
Received: July 24, 2019

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.
Acting Assistant 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)*

K191382

Device Name
IPS e.max® CAD Abutment Solutions- extra systems

Indications for Use *(Describe)*

IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

The system comprises three parts:
- IPS e.max CAD ceramic structure
- Ti base
- CAD/CAM system.

The IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.
The compatible Implant systems, titanium bases and CAD/CAM systems are shown below:
-Implant Systems:
- Dentsply Sirona: AstraTech OsseoSpeed, Frialit/Xive (K130999, K013867)
- BioHorizons Implant System: Internal Connection (K143022, K071638, K093321, K042429),
- Osstem: TS Implant System (K121585)
- Straumann: Tissue Level RN/WN (K061176)
- Nobel Biocare: Branemark (K022562)
- Zimmer: Tapered Screw-Vent (K061410)
- Camlog: Camlog Screw-Line, Conelog Screw-Line, iSy (K083496, K113779, K133991)

- CAD/CAM Systems: Sirona Dental CAD/CAM System (K181520)

-Titanium Bases:

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	Brånemark® NP	3.3	NP	NB B 3.4 L	6282516	L
	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	Tissue Level RN	4.8	RN (4.8)	S SO 4.8 L	6284249	L
	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	

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

IPS e.max® CAD Abutment Solutions- extra systems- K191382

Contact: Lori Aleshin, Director of Quality and Regulatory Affairs
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Date Prepared: August 26, 2019

Proprietary Name: **IPS e.max® CAD Abutment Solutions- extra systems**

Primary Classification Name: Abutment, Implant, Dental Endosseus (872.3630) (Classification Code NHA)

Secondary Classification Name: Dental Abutment Design Software for Dental Laboratory (872.3630) (Classification Code PNP)

Predicate/Reference Devices: IPS e.max® CAD Abutment Solutions (K132209) by Ivoclar Vivadent, AG
K100152 Sirona CAD/CAM System (Reference)
K111421 Sirona Dental CAD/CAM System (Reference)
K181520 Sirona Dental CAD/CAM System (Reference)

Device Description: The **IPS e.max® CAD Abutment Solutions- extra systems** which is the subject of this premarket notification is a modification to the IPS e.max CAD Abutment Solutions as previously cleared under K132209. The modifications represented in the subject device consist of the addition of 11 extra Ti-Bases to the 4 previously cleared Ti-Base compatibilities.

IPS e.max CAD Abutment Solutions- extra systems is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. IPS e.max CAD Abutment Solutions is a system comprising IPS e.max CAD ceramic structure, Sirona TiBase and Sirona CAD/CAM System to design and fabricate the ceramic structure. The abutments being two-piece titanium base abutments are mated with a ceramic top-half, in which the assembly comprises the final-finished medical device of a patient-specific dental abutment.

For the fabrication of IPS e.max CAD Abutment Solutions and depending on the CAD/CAM system used, the clinical situation is digitalized either by a direct intraoral scan or an indirect model scan. Updated material and TiBase library datasets relating to Sirona Dental CAD/CAM System with CEREC chairside software are obtained by download at: https://my.cerec.com.

510(K) SUMMARY

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

Existing Implant Systems (K132209)
Certain
Replace
Nobel Active
Bone Level

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
Branemark® NP
Branemark® RP
Osstem TS Mini
Osstem TS Standard
Tissue Level RN
Tissue Level WN
Tapered Screw-Vent 3.5
Tapered Screw-Vent 4.5
Tapered Screw-Vent 5.7
Camlog Screw-Line 3.3
Camlog Screw-Line 3.8
Camlog Screw-Line 4.3
Camlog Screw-Line 5.0
Camlog Screw-Line 6.0
Conelog Screw-Line 3.3
Conelog Screw-Line 3.8
Conelog Screw-Line 4.3
Conelog Screw-Line 5.0
iSy 3.8
iSy 4.4
iSy 5.0

Predicate Device: The primary predicate devices to which IPS e.max® CAD Abutment Solutions- extra systems has been compared is Ivoclar Vivadent, AG IPS e.max® CAD Abutment Solutions (K132209).

For this application, IPS e.max® 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

IPS e.max® CAD Abutment Solutions- extra systems is substantially equivalent to the predicate device.

The indications and working principle only differ in the fact, that IPS e.max CAD Abutment Solutions can now be used with 11 extra systems in addition to the predicate devices 4 implant systems (i.e., Replace, Nobel Active, Bone Level, Certain).

The fatigue testing performed for the listed extra systems proves that IPS e.max CAD Abutment Solutions can be used with the 11 additional implant systems.

Technological Characteristics	Proposed Device: IPS e.max CAD Abutment Solutions- extra systems (K191382)	Primary Predicate Device: IPS e.max® CAD Abutment Solutions (K132209)	Reference Device: Sirona 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 (summarized)	IPS e.max CAD Abutment Solutions is intended for use in partially of fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts: - IPS e.max CAD ceramic structure - Ti base and - CAD/CAM software	IPS e.max CAD Abutment Solutions is intended for use in partially of fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts: - IPS e.max CAD ceramic structure - Ti base and - CAD/CAM software	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.		
Compatibility	The IPS e.max CAD mesostructured and TiBase two-piece abutment is compatible with the following Implant Systems: - Dentsply Sirona: AstraTech OsseoSpeed, Frialit/Xive (K130999, K013867) - BioHorizons Implant System: Internal Connection (K143022, K071638, K093321, K042429), - Osstem: TS Implant System (K121585) - Straumann: Tissue Level RN/WN (K061176) - Nobel Biocare: Branemark (K022562)	The IPS e.max CAD mesostructured and TiBase two-piece abutment is compatible with the following Implant Systems: Certain (K014235) Nobel Biocare Replace (K020646) Nobel Biocare Activem (K071370) Straumann Bone Level (K053088	The InCoris mesostructured and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare: Replace (K020646)	The InCoris mesostructured and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646)	The InCoris mesostructured and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646) Nobel Biocare Active (K071370)

Technological Characteristics	Proposed Device: IPS e.max CAD Abutment Solutions- extra systems (K191382)	Primary Predicate Device: IPS e.max® CAD Abutment Solutions (K132209)	Reference Device: Sirona 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) - Camlog: Camlog Screw-Line, Conelog Screw-Line, iSy (K083496, K113779, K133991)		Nobel Biocare: Branemark (K022562) Friadent Xive (K013867) Biomet 3i Osseotite (K980549) AstraTech Osseospeed (K091239) Zimmer Tapered Screw-Vent (K061410) Straumann SynOcta (K061176)	Nobel Biocare Branemark (K022562) Friadent Xive (K013867) Biomet 3i Osseotite (K980549) AstraTech Osseospeed (K091239) Zimmer Tapered Screw-Vent (K061410) Straumann SynOcta (K061176) Straumann Bone Level (K053088, K062129, K060958)	Nobel Biocare Branemark (K022562) Straumann SynOcta (K061176) Straumann Bone Level (K053088, K062129, K060958) Dentsply Sirona Osseospeed (K091239) Xive (K013867) Dentsply Sirona Osseospeed EV (K130999) Dentsply Sirona Ankylos (K140347, K083805)

Technological Characteristics	Proposed Device: IPS e.max CAD Abutment Solutions- extra systems (K191382)	Primary Predicate Device: IPS e.max® CAD Abutment Solutions (K132209)	Reference Device: Sirona CAD/ CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
				Biomet 3i Certain (K014235, K061629) Nobel Biocare Active (K071370)	Biomet 3i Osseotite (K980549) Biomet 3i Certain (K014235, K061629) 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)

Technological Characteristics	Proposed Device: IPS e.max CAD Abutment Solutions- extra systems (K191382)	Primary Predicate Device: IPS e.max® CAD Abutment Solutions (K132209)	Reference Device: Sirona CAD/ CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
General Design	IPS e.max CAD Abutment Solutions are lithium disilicate 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 geometry to titanium bases is prefabricated, i.e. already included in the shipped block. The connection geometry fit select Titanium Bases as identified in the Indications for Use. The mesostructured is individually designed and milled using CAD/CAM Technology into the shape of a hybrid abutment or hybrid abutment crown. The device serves as the esthetic mesostructured which is extraorally cemented onto a Titanium Base. The two piece abutment is mounted onto the implant and fixed with a screw.	IPS e.max CAD Abutment Solutions are lithium disilicate 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 geometry to titanium bases is prefabricated, i.e. already included in the shipped block. The connection geometry fit select Titanium Bases as identified in the Indications for Use. The mesostructured is individually designed and milled using CAD/CAM Technology into the shape of a hybrid abutment or hybrid abutment crown. The device serves as the esthetic mesostructured which is extraorally cemented onto a Titanium Base. The two piece abutment is mounted onto the implant and fixed with a screw.	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: IPS e.max CAD Abutment Solutions- extra systems (K191382)	Primary Predicate Device: IPS e.max® CAD Abutment Solutions (K132209)	Reference Device: Sirona CAD/ CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
Abutment Angle	0° to 20°	0° to 20°	0° to 20°		
Restoration	Single Unit	Single Unit	Single Unit, Multi-Unit		
Implant Compatibility	Dentsply Sirona: AstraTech OsseoSpeed, Frialit/Xive - BioHorizons Implant System: Internal Connection - Osstem: TS Implant System - Straumann: Tissue Level RN/WN - Nobel Biocare: Branemark - Zimmer: Tapered Screw-Vent - Camlog: Camlog Screw-Line Conelog Screw-Line iSy	Certain Nobel Biocare Replace Nobel Biocare Activem Straumann Bone Level	Nobel Biocare-Replace, Branemark Friadent- Xive Biomet 3i- Osseotite Astra Tech-Osseospeed Zimmer- Tapered Screw-Vent Straumann-SynOcta	Nobel Biocare-Replace, Branemark Friadent Xive Biomet 3i-Osseotite, Certain Astra Tech-OsseoSpeed Zimmer- Tapered Screw-Vent Straumann-SynOcta, Bone Level Nobel Biocare-Nobel Active	Nobel Biocare-Replace, Active, Branemark Straumann-SynOcta , Bone Level Dentsply Sirona-Osseospeed, Xive, Osseospeed EV, Ankylos Biomet 3i-Osseotite, Certain Zimmer- Tapered Screw-Vent Thomenn Medical-SPI

Technological Characteristics	Proposed Device: IPS e.max CAD Abutment Solutions- extra systems (K191382)	Primary Predicate Device: IPS e.max® CAD Abutment Solutions (K132209)	Reference Device: Sirona CAD/ CAM System (K100152)	Reference Device: Sirona Dental CAD/CAM System (K111421)	Reference Device: Sirona Dental CAD/CAM System (K181520)
					Osstem/Hiossen- Osstem TS/ Hiossen BioHorizons- Internal Connections
Block Material	Lithium Disilicate	Lithium Disilicate	InCoris	InCoris	InCoris
Cement (Adhesive)	Multilink Hybrid Abutment	Multilink Hybrid Abutment	Panavia F2.0	Panavia F2.0	Panavia F2.0
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Sterilization Method	Steam Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization
Use	Single Use	Single Use	Single-Use	Single-Use	Single-Use

510(K) SUMMARY

Indications for Use Statement:

IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

The system comprises three parts:
- IPS e.max CAD ceramic structure
- Ti base
- CAD/CAM system.

The IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.
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- Osstem: TS Implant System (K121585)
- Straumann: Tissue Level RN/WN (K061176)
- Nobel Biocare: Branemark (K022562)
- Zimmer: Tapered Screw-Vent (K061410)
- Camlog: Camlog Screw-Line, Conelog Screw-Line, iSy (K083496, K113779, K133991)

- CAD/CAM Systems: Sirona Dental CAD/CAM System (K181520)

-Titanium Bases:

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	Brånemark® NP	3.3	NP	NB B 3.4 L	6282516	L
	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	Tissue Level RN	4.8	RN (4.8)	S SO 4.8 L	6284249	L
	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	

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:

The device design, i.e. delivery form and composition of IPS e.max CAD Abutment Solutions- extra systems and the predicate device are the same. The indications for use of the IPS e.max 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, Bårnemark®, Tissue Level, Tapered Screw-Vent, Camlog Screw-Line, Conelog Screw-Line, iSy, and Osstem TS). The submission is taking the previously cleared e.max CAD ceramic material and extending it's Ti-Base compatibilities to these additional Ti-Base abutments cleared under the referenced Sirona CAD/CAM System submissions.

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. Fatigue testing for the listed extra systems has been performed and discussed more fully in the Performance Testing- Bench (section 14) of this application.

Conclusion:

IPS e.max CAD Abutment Solutions- extra systems is substantially equivalent to the predicate device.