DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 15, 2016

Ivoclar Vivadent AG
% Donna Hartnett
Director QA/Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K160798
Trade/Device Name: IPS e.max® Press Abutment Solutions for Viteo Base Ti
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 4, 2016
Received: November 14, 2016

Dear Donna Hartnett:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for 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 Industry and Consumer Education 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,

Michael J. Ryan -S

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

Enclosure

Indications for Use

510(k) Number (if known): : K160798

Device Name: IPS e.max® Press Abutment Solutions for Viteo Base Ti

Indications For Use:

IPS e.max Press Abutment Solutions for Viteo Base Ti is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unit cement retained restorations.

IPS e.max Press Abutment Solutions is recommended for the fabrication of:

- Hybrid abutments for single-tooth restorations
- Hybrid abutment crowns for restorations

IPS e.max Press Abutment Solutions for Viteo Base-Ti are compatible with the following Implant Systems

Implant brand and type	Clearance ID	Platform and Implant Diameter(s)	
Straumann® Dental Implant System,	Bone Level® K150938 K130222	NC: 3.3 mm	RC: 4.1, 4.8 mm
Nobel Biocare®,	NobelActive® K071370 K041661	NP: 3.5 mm	RP: 4.3, 5.0 mm
Biomet 3i®	Osseotite® Certain® K111216	BI-OC: 3.4 mm	BI-OC: 4.1, 5.0 mm
Astra Tech AB	OsseoSpeed® K101732 K091239	OS: 3.5, 4.0 mm	OS: 4.5, 5.0 mm

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base - Ti

Contact: Donna Marie Hartnett

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

Date Prepared: December 14, 2016

Proprietary Name: **IPS e.max® Press Abutment Solutions for Viteo Base Ti**

Classification Name: Endosseous Dental Implant Abutment (872.3630)
(Classification Code NHA)

Device Description: IPS e.max Press Abutment Solutions for Viteo Base Ti is a prefabricated prosthetic component for endosseous dental implants to support prosthetic restorations in partially or fully edentulous jaws. The Viteo Base-Ti is the apical component of a two-piece abutment. A separate mesostructure fabricated out of IPS e.max Press ceramic is attached to the Viteo Base-Ti extraorally using Multilink Hybrid Abutment Cement (K130436). This part then serves as an intermediary to facilitate the connection of the 2-part abutment to the prosthetic material (crown). The abutment as a whole is intended to be used as an aid in prosthetic rehabilitation for the purpose of providing a suitable chewing function. A compatible screw is included with the Viteo Base-Ti for attachment of the completed hybrid abutment to the implant body. Alternatively, the mesostructure may be fabricated into the prosthetic restoration and attached to the Viteo Base-Ti via the screw to form a hybrid crown/abutment, thereby incorporating the top half of the two-piece abutment into the body of the crown.

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base - Ti

The Viteo Base Ti is made of Ti-6Al-4V ELI Titanium Grade 23 and is provided with a compatible screw made of the same materials. Viteo Base-Ti is available in two platform sizes (SD and MD) for various cleared implant systems as described in this summary. The upper part (pillar) of the Viteo Base Ti can be shortened individually, has a blasted surface to support bonding of the restorative part, and has an internal retentive lock to circumvent rotation. The IPS e.max Press Abutment Solutions for Viteo Base Ti are parts of the implant system which consists of:

- Implant Body – marketed by the Implant Manufacturer
- Viteo Base Ti – Titanium part Included in subject device
- Screw - Titanium screw Included in subject device
- IPS e.max Press – either as a part of the abutment or a Hybrid Abutment crown included in the subject device.
- Multilink Hybrid Abutment Cement – to bond together the Viteo Base Ti abutment part and the IPS e.max Press ceramic part included in the subject device.

Primary Predicate Device: IPS e.max Press Abutment Solutions (K120053)
Reference predicate device: IPS e.max Press Abutment Solutions for Nobel Biocare (K124008)

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base - Ti

Indications for Use

IPS e.max Press Abutment Solutions for Viteo Base Ti is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unit cement retained restorations.

IPS e.max Press Abutment Solutions is recommended for the fabrication of:

- Hybrid abutments for single-tooth restorations
- Hybrid abutment crowns for restorations

IPS e.max Press Abutment Solutions for Viteo Base-Ti are compatible with the following Implant Systems

Implant brand and type	Clearance ID	Platform and Implant Diameter(s)	
Straumann® Dental Implant System,	Bone Level® K150938 K130222	NC: 3.3 mm	RC: 4.1, 4.8 mm
Nobel Biocare®,	NobelActive® K071370 K041661	NP: 3.5 mm	RP: 4.3, 5.0 mm
Biomet 3i®	Osseotite® Certain® K111216	BI-OC: 3.4 mm	BI-OC: 4.1, 5.0 mm
Astra Tech AB	OsseoSpeed® K101732 K091239	OS: 3.5, 4.0 mm	OS: 4.5, 5.0 mm

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base Ti

Comparison to predicate device:

I) **Comparison Matrix (Table 1)**	**Subject Device**	**(C.) Predicate Device(s) (primary and reference)**	
Name of Company	Ivoclar Vivadent AG	Ivoclar Vivadent AG	Ivoclar Vivadent AG
Name of Device	IPS e.max Press Abutment Solutions for Viteo Base Ti	IPS e.max Press Abutment Solutions for Straumann Cementable abutment	IPS e.max PRESS Abutment Solutions for Nobel Biocare
510(k) number	K160798	*K120053 (Primary)*	*K124008 (Reference)*
Classification & Product Code	872.3630 - NHA	872.3630 - NHA	872.3630 - NHA
(D.) Intended use Indications for use	IPS e.max Press Abutment Solutions for Viteo Base Ti is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unit cement retained restorations. IPS e.max Press Abutment Solutions is recommended for the fabrication of: - Hybrid abutments for single-tooth restorations - Hybrid abutment crowns for restorations	IPS e.max® Press Abutment Solutions is intended for use in partially or fully endentuous mandibles and maxillae in support of single or multiple-unit cement retained restorations. IPS e.max Press Abutment Solutions is recommended for the fabrication of: - Hybrid abutments for single-tooth restorations - Hybrid abutment crowns for restorations	IPS e.max Press Abutment Solutions for Nobel Biocare is intended for use in partially or fully endentuous mandibles and maxillae in support of single or multiple-unit cement retained restorations. IPS e.max Press Abutment Solutions for Nobel Biocare is recommended for the fabrication of: - Hybrid abutments for single-tooth restorations - Hybrid abutment crowns for restorations

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base Ti

I) **Comparison Matrix (Table 1)**		**Subject Device**	**(C.) Predicate Device(s) (primary and reference)**	
Name of	Company	Ivoclar Vivadent AG	Ivoclar Vivadent AG	Ivoclar Vivadent AG
	Device	IPS e.max Press Abutment Solutions for Viteo Base Ti	IPS e.max Press Abutment Solutions for Straumann Cementable abutment	IPS e.max PRESS Abutment Solutions for Nobel Biocare
Compatible Abutment /Implant Systems		IPS e.max Press Abutment Solutions are compatible for use for use with the following implant systems: - Nobel Biocare® NobelActive® - Biomet 3i® Osseotite® Certain® - Straumann® Bone Level® - Astra Tech OsseoSpeed®	The following Ti bases and implant bodies are intended to be used with IPS emax Press Abutment Solutions - Straumann RC Cementable abutment D 5.0-6.5mm, GH 1-0-3.0mm, HTi 4.0-5.5mm - Straumann Bone Level RC Implant Ø4.1 or Ø4.8	The following Ti bases and implant bodies are intended to be used with IPS e.max Press Abutment Solutions for Nobel Biocare: - Nobel Snappy Abutment 4.0 internal tni-channel NP, RP, WP, 6.0 - NobelReplace Tapered Implant NP Ø3.5, RP Ø4.3, WP Ø5.0, Ø6.0 - Replace Select Tapered Implant NP Ø3.5, RP Ø4.3, WP Ø5.0, Ø6.0
(E.) Technological Characteristics				
pre-fabricated part(s)	Raw material Abutment	Ti-6Al-4V ELI	Ti-6Al-7Nb	Ti-6Al-4V
Design attributes	Angulation (implant vs. abutment axis)	straight i.e. 0°	straight i.e. 0°	straight i.e. 0°
	Collar-diameter	4.5 – 5.2 mm	5.0 – 6.5 mm	4.5 , 5.5, 6.5mm
	Height above collar	Nominal 6.0 mm; may shorten to 4.0mm	4.0 – 5.5 mm	7.0 mm
	Engaging / Non-Engaging	Engaging	Engaging	Engaging
	Fixation	Abutment Screw	Abutment Screw	Abutment Screw
	Bonding Surface	Blasted 50µm	n.s.	n.s.
	Raw material Screw	Ti-6Al-4V ELI	Ti-6Al-7Nb	Ti-6Al-4V

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base Ti

I) **Comparison Matrix (Table 1)**	**Subject Device**	**(C.) Predicate Device(s) (primary and reference)**	
Name of Company	Ivoclar Vivadent AG	Ivoclar Vivadent AG	Ivoclar Vivadent AG
Device	IPS e.max Press Abutment Solutions for Viteo Base Ti	IPS e.max Press Abutment Solutions for Straumann Cementable abutment	IPS e.max PRESS Abutment Solutions for Nobel Biocare
Illustration of pre-fabricated part			

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base Ti

I) **Comparison Matrix (Table 1)**

		Subject Device	**(C.) Predicate Device(s) (primary and reference)**	
Name of	Company	Ivoclar Vivadent AG	Ivoclar Vivadent AG	Ivoclar Vivadent AG
	Device	IPS e.max Press Abutment Solutions for Viteo Base Ti	IPS e.max Press Abutment Solutions for Straumann Cementable abutment	IPS e.max PRESS Abutment Solutions for Nobel Biocare
restorative part (abutment crown) – Design attributes	Material(s) for Abutment Crown	Ceramic Ingots *(i.e. IPS e.max® press family)*	Ceramic Ingots *(i.e. IPS e.max® press family)*	Ceramic Ingots *(i.e. IPS e.max® press family)*
	Retaining of Crown	By cementation	By cementation	By cementation
	Max. angulation *(implant- vs. crown axis)*	Angular correction allowed between 0°–20°	Angular correction allowed between 0°–20°	Angular correction allowed between 0°–20°
	Final Height	Set by Dental technician	Set by Dental technician	Set by Dental technician
Process constraints /workflows	Applicable technique(s) for Abutment Crown	Press techniques	Press technique	Press technique
	Intended Design Workflows	wax-up	wax-up	wax-up
	Manufacturing Workflow	traditional	traditional	traditional
(F.) Performance Data (pre-fabricated part)				
Mechanical	Fatigue	Worst case evaluation was done for each implant type listed in Table 1. The dynamic fatigue test for endosseous implants acc. ISO 14801 demonstrated that the tested implants systems containing the corresponding Viteo-Abutment run-out successfully.	The dynamic fatigue test for endosseous implants acc. ISO 14801 demonstrated that the tested Straumann implant system run-out successfully.	The dynamic fatigue test for endosseous implants acc. ISO 14801 demonstrated that the tested Nobel implant system run-out successfully.
Microbial	Sterile	Not delivered sterile	Not delivered sterile	Not delivered sterile
	Re-useable	Single use only	Single use only	Single use only

510(K) SUMMARY

IPS e.max Press Abutment Solutions for Viteo Base Ti

Testing Summary:

The following performance testing was submitted in this 510K application to support substantial equivalence:

- Worst case dynamic fatigue testing according to ISO 14801: Dynamic Fatigue Testing, considering the FDA Guidance Class II Special Controls for Root form Endosseous Dental Implants and Endosseous Dental Abutments. Fatigue results shown in previously cleared titanium bases for the predicate device did not substantially differ from the test results shown for Viteo Base Ti.
- Sterilization validation according to ISO 17665-1, ISO/TR 17665-2 and ANSI/AAMI ST79
- Compatibility of the Viteo Base Ti interface to the implant bodies listed above was verified by measuring Data & tolerance analysis which demonstrated that the Viteo Base-Ti dimensional specifications are compatible with the appropriate implant system.

Biocompatibility:

The subject device was evaluated for Biocompatibility according to ISO 10993-1 and ISO 7405. The material was tested for corrosion according to ISO 10271:2011 and EN ISO 22674:2006 and met the requirements for those standards for total ion release and electrochemical test. The chemical composition is according to ASTM F136-08. The blasted surface is not exposed to the oral environment as the mesostructured or hybrid crown is luted with self-curing cement to the blasted surface extraorally. Therefore, additional biocompatibility testing of the Viteo Base-Ti with blasted surface was not conducted based on risk assessment. The fabricated articles are subject to a cleaning procedure. A documented cleaning validation proves that the surface is free from any remaining contaminant after the surface blasting procedure. Before inserting the fabricated abutment into the patient's mouth, a steam sterilization is recommended in the instructions for use. This does not alter the surface and provides a final cleaning step. The material was also evaluated for hypersensitivity/sensitization, irritation, acute and subchronic systemic toxicity – oral/inhalation, genotoxicity and Implantation with passing results.

Conclusion: The documentation submitted in this premarket notification demonstrates that the IPS e.max Press Abutment Solutions for Viteo Base Ti are substantially equivalent to the primary predicate IPS e.max Press Abutment Solutions (K120053).