DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 30, 2016

Vita Zahnfabrik H. Rauter GmbH Co.
% Ms. Nevine Erian
Director, Regulatory Affairs & Compliance (consultant)
Vita North America, Inc.
22705 Savi Ranch Parkway, Suite 100
Yorba Linda, California 92887

Re: K153645
Trade/Device Name: VITA ENAMIC® Implant Solutions (IS)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 27, 2016
Received: June 3, 2016

Dear Ms. Erian:

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,

for Erin I. Keith, M.S.
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) K153645

Device Name VITA ENAMIC® Implant Solutions (IS)

Indications for Use

VITA ENAMIC Implant Solutions is indicated for use as a component of a two-piece abutment system, consisting of a tibase component, and a mesostructure or abutment crown. VITA ENAMIC Implant Solutions is intended for use in partially or fully edentulous mandible or maxillae for fabrication of permanent, anterior or posterior, single unit CAD/CAM abutments. VITA ENAMIC Implant Solutions is indicated for use in conjunction with the CAD/CAM component of the Sirona Dental CAD/CAM system and the following Tibase abutments and implant bodies:

Table 1 – Compatible Sirona Ti Base/Implant System and VITA ENAMIC IS Interface

Sirona TiBase Type	Abutment Screw	Sirona Part #	VITA ENAMIC IS Interface	Implant Manufacturer	Implant System	Implant Diameter
NBRS 3.5	M1.8	6282474	L	Nobel Biocare	Replace® NP	3.5 mm
NBRS 4.3	M2	6282482	L		Replace® RP	4.3 mm
NBRS 5.0	M2	6282490	L		Replace® WP	5.0 mm
NBRS 6.0	M2	6282508	L		Replace® 6.0	6.0 mm
NBB 3.4	M1.6	6282516	L	Nobel Biocare	Brånemark®	3.3 mm
NBB 4.1	M2	6282524	L		Brånemark®	3.75 / 4.0 mm
NB A 4.5	M1.6	6308188	L	Nobel Biocare	Nobel Active NP	3.5 mm
NB A 5.0	M2	6308253	L		Nobel Active RP	4.3 / 5.0 mm
SSO 3.5	M1.8	6284231	L	Straumann®	Tissue level NN	3.5 mm
SSO 4.8	M2	6284249	L		Tissue Level RN	4.8 mm
SSO 6.5	M2	6284256	L		Tissue Level WN	6.5 mm
S BL 3.3	M1.6	6308154	L	Straumann®	Bone Level NC	3.3mm
S BL 4.1	M1.6	6308337	L		Bone Level NC	4.1 / 4.8 mm
ATOS 3.5/4.0	M1.6	6282532	L	Astra Tech	OsseoSpeed™	3.5 S/4.0 S mm
ATOS 4.5/5.0	M1.6	6282540	L		OsseoSpeed™	4.5 / 5.0 mm
FX 3.4	M1.6	6282433	S	Friadent	Frialit®Xive®	3.4 mm
FX 3.8	M1.6	6282441	S		Frialit®Xive®	3.8 mm
FX 4.5	M1.6	6282458	L		Frialit®Xive®	4.5 mm
FX 5.5	M1.6	6282466	L		Frialit®Xive®	5.5 mm
BO 3.4	M2	6282557	L	Biomet 3i	Ex. hex	3.4 mm
BO 4.1	M2	6282565	L		Ex. hex	4.1 mm
BO 5.0	M2	6282573	L		Ex. hex	5.0 mm
B C 3.4	M1.6	6308048	S	Biomet 3i	Certain®	3.5 mm
B C 4.1	M1.6	6308097	L		Certain®	4.5 mm
B C 5.0	M1.6	6308121	L		Certain®	5.7 mm

Table 1 – Compatible Sirona Ti Base/Implant System and VITA ENAMIC IS Interface						
Sirona TiBase Type	**Abutment Screw**	**Sirona Part #**	**VITA ENAMIC IS Interface**	**Implant Manufacturer**	**Implant System**	**Implant Diameter**
ZTSV 3.5	M1.8	6282581	L	Zimmer	Tapered screw-Vent®	3.5 mm
ZTSV 4.5	M1.8	6282599	L		Tapered screw-Vent®	4.5 mm
ZTSV 5.7	M1.8	6282607	L		Tapered screw-Vent®	5.7 mm

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K153645

510(k) Summary

Submitter

Vita Zahnfabrik H.Rauter GmbH Co.
Spitelgasse 3
Bad Sackingen, D-79713
Germany
Establishment Reg. No. 1000625496

Contact

Bernd Walker
Head of Regulatory Affairs and Quality Systems
Phone (+49) 7761/562-361
Fax (+49) 7761/562-384

Official Correspondent

Nevine Erian
Director, Regulatory Affairs & Compliance (Consultant)
VITA North America, Inc.
22705 Savi Ranch Parkway, Suite 100
Yorba Linda, CA 92887
Establishment Reg. No. 2082832
Phone (949) 370-7155
Fax (714) 221-6759
E-mail: nerian@vident.com

Date Prepared June 30, 2016

- **Trade/Device Name** VITA ENAMIC® Implant Solutions (IS)
- **Common Name** Abutment, implant, dental, endosseous
- **Classification Name** Endosseous Dental Implant Abutment
- **Regulation Number** 21 CFR 872.3630
- **Product Code** NHA

Predicate Devices

inCoris ZI meso (Sirona Dental) – K111421 – *Primary Predicate*
VITA ENAMIC® (VITA Zahnfabrik GmbH) – K122269
IPS e.max® CAD Abutment Solutions (Ivoclar Vivadent) – K132209

Device Description

VITA ENAMIC Implant Solutions (IS) is a hybrid ceramic CAD/CAM block, consisting of ~86% (by weight) feldspar ceramic and ~14% polymer.

The VITA ENAMIC Implant Solutions is milled then bonded to a titanium (Ti) base for a two-element solution with mesostructure or a single-element solution with abutment crown. The compatible Ti bases to VITA ENAMIC IS block interface size and CAD/CAM system are as follows:

Ti Base: Sirona TiBase (K111421)

CAD/CAM System: Sirona software – inlab 15.0 and above
Sirona software – CEREC 4.4 and above

Titanium Bases: Compatible titanium bases are shown in Table 1.

Table 1 – Compatible Sirona Ti Base/Implant System and VITA ENAMIC IS Interface

Sirona TiBase Type	Abutment Screw	Sirona Part #	VITA ENAMIC IS Interface	Implant Manufacturer	Implant System	Implant Diameter
NBRS 3.5	M1.8	6282474	L	Nobel Biocare	Replace® NP	3.5 mm
NBRS 4.3	M2	6282482	L		Replace® RP	4.3 mm
NBRS 5.0	M2	6282490	L		Replace® WP	5.0 mm
NBRS 6.0	M2	6282508	L		Replace® 6.0	6.0 mm
NBB 3.4	M1.6	6282516	L	Nobel Biocare	Brånemark®	3.3 mm
NBB 4.1	M2	6282524	L		Brånemark®	3.75 / 4.0 mm
NB A 4.5	M1.6	6308188	L	Nobel Biocare	Nobel Active NP	3.5 mm
NB A 5.0	M2	6308253	L		Nobel Active RP	4.3 / 5.0 mm
SSO 3.5	M1.8	6284231	L	Straumann®	Tissue level NN	3.5 mm
SSO 4.8	M2	6284249	L		Tissue Level RN	4.8 mm
SSO 6.5	M2	6284256	L		Tissue Level WN	6.5 mm
S BL 3.3	M1.6	6308154	L	Straumann®	Bone Level NC	3.3mm
S BL 4.1	M1.6	6308337	L		Bone Level NC	4.1 / 4.8 mm
ATOS 3.5/4.0	M1.6	6282532	L	Astra Tech	OsseoSpeed™	3.5 S/4.0 S mm
ATOS 4.5/5.0	M1.6	6282540	L		OsseoSpeed™	4.5 / 5.0 mm
FX 3.4	M1.6	6282433	S	Friadent	Frialit®Xive®	3.4 mm
FX 3.8	M1.6	6282441	S		Frialit®Xive®	3.8 mm
FX 4.5	M1.6	6282458	L		Frialit®Xive®	4.5 mm
FX 5.5	M1.6	6282466	L		Frialit®Xive®	5.5 mm
BO 3.4	M2	6282557	L	Biomet 3i	Ex. hex	3.4 mm
BO 4.1	M2	6282565	L		Ex. hex	4.1 mm
BO 5.0	M2	6282573	L		Ex. hex	5.0 mm
B C 3.4	M1.6	6308048	S	Biomet 3i	Certain®	3.5 mm
B C 4.1	M1.6	6308097	L		Certain®	4.5 mm
B C 5.0	M1.6	6308121	L		Certain®	5.7 mm
ZTSV 3.5	M1.8	6282581	L	Zimmer	Tapered screw-Vent®	3.5 mm
ZTSV 4.5	M1.8	6282599	L		Tapered screw-Vent®	4.5 mm
ZTSV 5.7	M1.8	6282607	L		Tapered screw-Vent®	5.7 mm

Statement of Intended Use

VITA ENAMIC Implant Solutions is indicated for use as a component of a two-piece abutment system, consisting of a tibase component, and a mesostructure or abutment crown. VITA ENAMIC Implant Solutions is intended for use in partially or fully edentulous mandible or maxillae for fabrication of permanent, anterior or posterior, single unit CAD/CAM abutments. VITA ENAMIC Implant Solutions is indicated for use in conjunction with the CAD/CAM component of the Sirona Dental CAD/CAM system and the following Tibase abutments and implant bodies:

Table 1 – Compatible Sirona Ti Base/Implant System and VITA ENAMIC IS Interface

Sirona TiBase Type	Abutment Screw	Sirona Part #	VITA ENAMIC IS Interface	Implant Manufacturer	Implant System	Implant Diameter
NBRS 3.5	M1.8	6282474	L	Nobel Biocare	Replace® NP	3.5 mm
NBRS 4.3	M2	6282482	L		Replace® RP	4.3 mm
NBRS 5.0	M2	6282490	L		Replace® WP	5.0 mm
NBRS 6.0	M2	6282508	L		Replace® 6.0	6.0 mm
NBB 3.4	M1.6	6282516	L	Nobel Biocare	Brånemark®	3.3 mm
NBB 4.1	M2	6282524	L		Brånemark®	3.75 / 4.0 mm
NB A 4.5	M1.6	6308188	L	Nobel Biocare	Nobel Active NP	3.5 mm
NB A 5.0	M2	6308253	L		Nobel Active RP	4.3 / 5.0 mm
SSO 3.5	M1.8	6284231	L	Straumann®	Tissue level NN	3.5 mm
SSO 4.8	M2	6284249	L		Tissue Level RN	4.8 mm
SSO 6.5	M2	6284256	L		Tissue Level WN	6.5 mm
S BL 3.3	M1.6	6308154	L	Straumann®	Bone Level NC	3.3mm
S BL 4.1	M1.6	6308337	L		Bone Level NC	4.1 / 4.8 mm
ATOS 3.5/4.0	M1.6	6282532	L	Astra Tech	OsseoSpeed™	3.5 S/4.0 S mm
ATOS 4.5/5.0	M1.6	6282540	L		OsseoSpeed™	4.5 / 5.0 mm
FX 3.4	M1.6	6282433	S	Friadent	Frialit®Xive®	3.4 mm
FX 3.8	M1.6	6282441	S		Frialit®Xive®	3.8 mm
FX 4.5	M1.6	6282458	L		Frialit®Xive®	4.5 mm
FX 5.5	M1.6	6282466	L		Frialit®Xive®	5.5 mm
BO 3.4	M2	6282557	L	Biomet 3i	Ex. hex	3.4 mm
BO 4.1	M2	6282565	L		Ex. hex	4.1 mm
BO 5.0	M2	6282573	L		Ex. hex	5.0 mm
B C 3.4	M1.6	6308048	S	Biomet 3i	Certain®	3.5 mm
B C 4.1	M1.6	6308097	L		Certain®	4.5 mm
B C 5.0	M1.6	6308121	L		Certain®	5.7 mm
ZTSV 3.5	M1.8	6282581	L	Zimmer	Tapered screw-Vent®	3.5 mm
ZTSV 4.5	M1.8	6282599	L		Tapered screw-Vent®	4.5 mm
ZTSV 5.7	M1.8	6282607	L		Tapered screw-Vent®	5.7 mm

Material Composition

VITA ENAMIC IS is identical in composition to VITA ENAMIC (K122269).

Technological Characteristics

VITA ENAMIC IS is offered in a block form, with a mandrel attachment, to permit securing it into a CAD/CAM machine for milling into its final form.

The VITA ENAMIC IS blocks have a pre-drilled hole compatible with Sirona TiBase (K111421) to allow the mesostructure or abutment crown bonded to a titanium base to be connected to the implant. VITA ENAMIC IS blocks are identical to VITA ENAMIC blocks (K122269) in geometry, with the exception of a pre-drilled hole.

Because the subject device and its predicates inCoris Zl meso, IPS e.max CAD Abutment Solutions do not share similar chemical or physical properties, a reference device, VITA Enamic, was introduced by the sponsor. The differences between VITA ENAMIC IS and the predicate devices do not render the subject device not substantially equivalent for the following reasons:

- VITA ENAMIC IS has non-identical, but similar indications as the inCoris Zl meso and IPS e.max CAD Abutment Solutions, and meets the same biocompatibility, ISO 6872:2008 and ISO 14801:2007 test criteria. While the verbiage of the indications for use statements differs, the intended use for each is similar. All three are restorative blocks intended to serve as milled components of dental implant abutments and abutment crowns, and all three share implant compatibilities with the same Sirona TiBase devices.
- VITA ENAMIC IS has the identical chemical composition and physical properties as VITA ENAMIC.

As such, the data supports the substantial equivalence of the subject and predicate devices.

Non-Clinical Performance Testing

VITA ENAMIC IS meets the applicable requirements of the following FDA recognized standards:

- ISO 6872:2008 – Dentistry – Ceramic materials
- ISO 10477:2004(E) – Dentistry – Polymer-based crown and bridge materials standard.

- ISO 14801:2007 – Dentistry – Implants – Dynamic fatigue test for endosseous dental implants

Bench test results allowed us to conclude that VITA ENAMIC IS is well suited for its intended use.

Biocompatibility

A biocompatibility assessment was performed on VITA ENAMIC IS in accordance with ISO 10933-1:2009 – *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,* and ISO 7405:2008 – *Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry.* Testing from reference device VITA ENAMIC was leveraged to support biocompatibility. This assessment supports that VITA ENAMIC IS is biocompatible and concludes that the device is compatible for its intended use.

Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of VITA ENAMIC IS.

Substantial Equivalence

Material

VITA ENAMIC IS has the identical chemical composition as the predicate device, VITA ENAMIC (K122269).

Physical Properties

VITA ENAMIC IS has identical physical properties as the predicate device, VITA ENAMIC (K122269).

Technical Comparison of VITA ENAMIC IS to Predicate Devices

Technical Attributes	**VITA ENAMIC IS**	**inCoris ZI meso**	**IPS e.max CAD Abutment Solutions**	**VITA ENAMIC**
Indication	Implant Abutment and Abutment Crown	Implant Abutment and Abutment Crown	Implant Abutment and Abutment Crown	Crown & Veneers
CAD/CAM Material	Yes	Yes	Yes	Yes
Physical Configuration	Block with a pre-drilled hole and mandrel attachment	Block with a pre-drilled hole and mandrel attachment	Block with a pre-drilled hole and mandrel attachment	Block with mandrel attachment

Technical Attributes	VITA ENAMIC IS	inCoris ZI meso	IPS e.max CAD Abutment Solutions	VITA ENAMIC
Block Sizes	12 x 14 x 18 mm and 18 x 16 x 18 mm with Small or Large hole size	One block size with Small or Large hole size	12.4 x 14.5 x 18.0 mm and 17.8 x 15.8 x 18.0 mm with Small or Large hole size	12 x 14 x 18 mm and 8 x 10 x 15 mm with Small or Large hole size
Shades & Translucency	Different shades Translucent & High Translucent	Two shades	Different shades Medium Opacity & Low Translucency	Different shades Translucent & High Translucent
Bonds to Titanium Base	Sirona TiBase with Small & Large hole	Sirona TiBase with Small & Large hole	Sirona TiBase with Small & Large hole	No
Maximal Abutment Angulation	20°	20°	20°	Not applicable
Abutment Fixation	Screwed	Screwed	Screwed	Not applicable
Screw	Part of implant system	Part of implant system	Part of implant system	Not applicable
Compatible Titanium Base	Sirona TiBase (K11142)	Sirona TiBase (K11142)	Sirona TiBase (K11142)	Not applicable
1 or 2 piece Abutment	2 piece – ENAMIC IS to TiBase	2 piece – Incoris ZI to TiBase	2 piece – IPS e.max CAD to TiBase	Not applicable
Mechanical Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Not applicable
Flexural Strength	140 ± 10 MPa	> 900 MPa	360 ± 60 MPa	140 ± 10 MPa
Fracture Toughness	1.5 MPa $m^{0.5}$	5.9 Mpa $m^{0.5}$	2.0 – 2.5 MPa $m^{0.5}$	1.5 MPa $m^{0.5}$
Young's Modulus of Elasticity	30 GPa	Unknown	95 ± 5 GPa	30 GPa

Conclusion

Information provided by VITA North America, Inc. demonstrates that VITA ENAMIC Implant Solutions is substantially equivalent to the predicate devices. VITA ENAMIC IS shares the same indications and similar physical properties as the nCoris ZI meso and IPS e.max CAD Abutment Solutions. VITA ENAMIC IS has identical chemical composition and physical properties as VITA ENAMIC. Comparisons of the indications for use, chemical composition, technological characteristics and physical properties of VITA ENAMIC IS to the predicate devices all support the substantial equivalence of VITA ENAMIC Implant Solutions to its predicate devices.