DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 30, 2015

Vita Zahnfabrik H. Rauter Gmbh & Co.
c/o Ms. Nevine Erian
Director, Regulatory Affairs & Compliance
Vita North America, Inc.
22705 Savi Ranch Parkway, Suite 100
Yorba Linda, California 92887

Re: K152373
Trade/Device Name: VITA VM® LC Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 1, 2015
Received: December 2, 2015

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): K152373

Device Name: VITA **VM®LC** *Flow*

Indications for Use:

- Full and partial veneering of metal frameworks: crowns, bridges, telescopic crowns, implant superstructure
- Individualization of and layering on VITA ENAMIC®
- Layering-over long-term temporaries made from VITA CAD-Temp®
- Individualization of acrylic teeth
- Reproduction of gingival components
- Metal-free crowns and three-unit anterior bridges as long-term temporary restorations
- Veneering of removable and partially removable dentures (according to the manufacturer's information)
- Inlays
- Veneers

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 ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
(Division Sign Off)
Division of Dental, Infection Control and General Hospital Devices

510(k) Number

Prescription Use _____ OR Over-The-Counter Use_____
(Par. 21 CFR 801.109)

Section 5 – 510(k) Summary – K152373

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Date Prepared	December 29, 2015

- **Trade/Device Name** VITA VM® LC Flow
- **Common Name** Dental Veneering Material
- **Classification Name** Tooth Shade Resin Material
- **Regulation Number** 21 CFR 872.3690
- **Product Code** EBF

Predicate Devices

VITA Zeta® (VITA Zahnfabrik GmbH) – K961434 – *Primary Predicate*

SR Nexco® (Ivoclar Vivadent, AG) – K123304 – *Reference Predicate*

SINFONY® (ESPE Dental, AG) – K992645 – *Reference Predicate*

Device Description

VITA VM LC Flow is a light-cured microparticle indirect composite material for fixed and removable restorations for extraoral fabrication.

Statement of Intended Use

- Full and partial veneering of metal frameworks: crowns, bridges, telescopic crowns, implant superstructure
- Individualization of and layering on VITA ENAMIC®
- Layering-over long-term temporaries made from VITA CAD-Temp®
- Individualization of acrylic teeth
- Reproduction of gingival components
- Metal-free crowns and three-unit anterior bridges as long-term temporary restorations
- Veneering of removable and partially removable dentures (according to the manufacturer‘s information)
- Inlays
- Veneers

Material Composition

VITA VM LC Flow pastes consist of a mixture of dimethacrylates and filler particles.

Technological Characteristics

VITA VM LC Flow is classified as Type 2, Class 2, Polymer-based crown and bridge materials whose setting is effected by the application of energy from an external source, such as heat and/or light or UV radiation, Polymer-based crown and bridge materials that contain a light or UV-sensitive initiator , per ISO 10477:2004(E) – *Dentistry – Polymer-based crown and bridge materials* standard.

Biocompatibility

A biocompatibility assessment was performed on VITA VM LC Flow, 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.* Based on the assessment, biocompatibility testing was determined not necessary. This assessment supports that

VITA VM LC Flow is biocompatible.

Substantial Equivalence

VITA VM LC Flow shares the same intended use as the predicate devices. VITA VM LC Flow is comprised of same materials as the predicate devices. VITA VM LC Flow shares similar indications, chemical composition, technological characteristics and physical properties as the predicate devices. Any differences between VITA VM LC Flow and its predicates do not affect substantial equivalence as VITA VM LC Flow meets same biocompatibility requirements and ISO 10477 physical property requirements as the predicate devices.

Information provided in this application demonstrates that VITA VM LC Flow is substantially equivalent to the predicate devices.

Technical Comparison of VITA VM LC Flow to Predicate Devices

	VITA VM LC Flow	**VITA Zeta** *(Primary Predicate)*	**SR Nexco** *(Reference Predicate)*	**SINFONY** *(Reference Predicate)*
Indications for Use				
▪ Full & Partial veneering of metal frameworks: crowns, bridges, telescopic crowns, implant superstructures	Yes	Yes	Yes	Yes
▪ Veneering of acrylic resin frameworks	Yes	Yes	Yes	Yes
▪ Layering-over long-term temporaries	Yes	Yes	Yes	Yes
▪ Individualization of acrylic teeth	Yes	Yes	Yes	Yes
▪ Metal-free crowns & three-unit anterior bridges as long-term temporary restorations	Yes	Yes	Yes	Yes
▪ Inlays	Yes	Yes	Yes	Yes
▪ Onlays	No	Yes	Yes	Yes
▪ Veneers	Yes	Yes	Yes	Yes
Technological Aspect				
▪ Light-Cured Material	Yes	Yes	Yes	Yes
▪ Physical Configuration	Paste	Paste & Powder	Paste	Paste

▪ Material Composition	All are made of Methacrylate resins, photo-initiators, inorganic fillers and pigments			
ISO 10477 – Physical Property	All Pass			
▪ Flexural Strength	135 MPa	95 MPa	90 ± 10 MPa	105 MPa
▪ E-Modulus	6600 - 7500 MPa	3450 MPa	6500 ± 500 MPa	3100 MPa
▪ Water Absorption	25.4 µg/mm³	28 - 30 µg/mm^3	15 ± 1 µg/mm³	≈ 20 µg/mm³
▪ Water Solubility	0.1 µg/mm³	0 µg/mm^3	1 ± 0.5 µg/mm³	0.5 µg/mm³

Non-Clinical Performance Testing

Bench testing was performed in accordance with FDA recognized standard, ISO 10477:2004(E) – *Dentistry – Polymer-based crown and bridge materials* standard. VITA VM LC Flow meets applicable ISO 10477 criteria for the designated indications.

Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of VITA VM LC Flow.

Conclusion

Non-clinical performance testing of VITA VM LC Flow demonstrates that VITA VM LC Flow is as safe and effective for its intended use, and performs as well as the legally marketed predicate devices.