January 29, 2020

VITA Zanhnfabrik H. Rauter GmbH Co.
% Lindsay Tilton
Regulatory Affairs & Compliance (Consultant)
VITA North America
22705 Savi Ranch Parkway, Sutie 100
Yorba Linda, California 92887

Re: K191926
Trade/Device Name: VITA VIONIC Bond
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: December 20, 2019
Received: December 30, 2019

Dear Lindsay Tilton:

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 “Nandu” 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191926

Device Name
VITA VIONIC Bond

Indications for Use *(Describe)*
VITA VIONIC Bond is used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K191926

510(k) Summary

Submitter

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Date Prepared January 24, 2020

- **Trade/Device Name** VITA VIONIC® Bond
- **Classification Name** Denture relining, repairing, or rebasing resin
- **Regulation Number** 21 CFR 872.3760
- **Product Code** EBI

Predicate and Reference Predicate Devices

IvoBase CAD Bond, and Modelling Liquid – K151142 – *Primary Predicate Device*

Tokuyama Curegrace – K170549 – *Reference Predicate Device*

Device Description

VITA VIONIC® Bond is a two-component glue, mainly composed of acrylate polymers based on methyl methacrylate and used to fix artificial teeth in the milled denture base. VITA VIONIC® component I comes in a glass jar with a screw top lid and VITA VIONIC® Bond component II comes in a glass bottle with a screw top cap. Component II is mixed into component I by stirring until no streaks are visible. A thin film is then applied to all Bonding surfaces and then the artificial teeth are placed into the denture base and VITA VIONIC® Bond is allowed to cure. Comes in one, colorless shade.

This product is provided non-sterile.

Indications for use

VITA VIONIC® Bond is used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.

Material Composition

VITA VIONIC® Bond is mainly composed of acrylate polymers based on methyl methacylate (MMA)

Non-Clinical Performance Testing

VITA VIONIC® Bond was evaluated according to the following FDA recognized standards:

- DIN EN ISO 20795-1:2013 - Dentistry – Base polymers – Part 1: Denture base polymers (ISO 20795-1:2013)
    - This standard mainly refers to the requirements for a denture base. VITA VIONIC® Bond, bonds the artificial teeth to the denture base, which is tested under section 8.7 “Bonding to synthetic polymer teeth”
    - Section 8.9: Water solubility and water sorption
- ISO 10993-1:2009 – Biological evaluation of medical devices
- ISO 7405:2004 – Dentistry – Evaluation of biocompatibility of medical devices
- A Chemical Analysis was conducted on VITA VIONIC® Bond and the Residual monomer content were found to be below the limit values.

Bench test results allowed us to conclude that VITA VIONIC® Bond is substantially equivalent to the predicate device for its intended use.

Biocompatibility

A biocompatibility assessment was performed on VITA VIONIC® Bond in accordance with ISO 10993-1:2009 – *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.* This assessment supports that VITA VIONIC® Bond is biocompatible and concludes that the device is substantially equivalent to the predicate device for its intended use based on the following:

Biocompatibility tests were conducted on VITA VIONIC Bond for cytotoxicity, sensitization, irritation and intracutaneous reactivity, and genotoxicity.

- Cytotoxicity and genotoxicity and the results showed no cytotoxic or genotoxic results
- Irritation and sensitization risks were evaluated and found to be low

Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of VITA VIONIC® Bond.

Comparison to Predicate Devices

	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name	VITA VIONIC® Bond	IvoBase Bond and Modelling Liquid	Tokuyama Cure Grace
Device Classification	Denture relining, repairing, or rebasing resin	Denture relining, repairing, or rebasing resin	Denture relining, repairing, or rebasing resin
Product Code	EBI	EBI	EBI,EBG
Indication for use	Used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases	For the fabrication of removable dentures, e.g.: -partial and complete denture	An acrylic resin used in a variety of dental application such as: -Temporary inlay,

		prosthetics Hybrid denture prosthetics -Combined denture prosthetics -Mouth guards -Implant-supported denture prosthetics	crowns and bridges -Repair of broken or cracked dentures -Denture border extension -Replacement of lost denture teeth -Adjustment of occlusal height of resin teeth
Components	Liquid and Liquid	Powder and Liquid	Powder and Liquid
Principle of operation	Cured by chemical polymerization reaction starting with mixing the liquid and liquid component. (Self-curing)	Cured by chemical polymerization reaction starting with mixing the powder and liquid component. (Self-curing)	Cured by chemical polymerization reaction starting with mixing the powder and liquid component. (Self-curing)

Conclusion

Information provided in this application demonstrates that VITA VIONIC® Bond is substantially equivalent to the predicate devices.