November 22, 2021

VITA Zahnfabrik GmbH H Rauter & Co
% Lindsay Tilton
Regulatory Affairs Consultant
VITA North America
22705 Savi Ranch Parkway, Suite 100
Yorba Linda, California 92887

Re: K211854
Trade/Device Name: VITA Akzent LC
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material For Resin Fillings
Regulatory Class: Class II
Product Code: EBD
Dated: August 25, 2021
Received: August 27, 2021

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 Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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)*
K211854

Device Name
VITA Akzent LC

Indications for Use *(Describe)*
VITA AKZENT LC Indication range:
- Restorations made of hybrid ceramic
- Restorations made of light-curing veneering material
- Restorations made of CAD/CAM composites
- Prefabricated Teeth
- Denture 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.

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510(k) Summary

K211854

Submitter

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Date Prepared November 16,2021

- **Trade/Device Name** **Vita** Akzent® LC
- **Classification Name** Coating Material for Resin Filling
- **Regulation Number** 21 CFR 872.3310
- **Product Code** EBD

Predicate Devices

Vident's VITA Enamic Stains– K123761 – *Primary Predicate Device*

GC America's Optiglaze – K133836 – *Reference Device*

Device Description

VITA Akzent® LC VITA AKZENT LC is a light-curing methacrylate-based stain/ glaze system for extraoral surface characterization of dental restorations made of hybrid ceramic, resin veneering materials, CAD/CAM composites, prefabricated teeth and denture base resins. It can also be used for internal characterization with the layering technique of veneering composites.

Indications for Use

VITA AKZENT LC Indication range:
- Restorations made of hybrid ceramic
- Restorations made of light-curing veneering material
- Restorations made of CAD/CAM composites
- Prefabricated Teeth
- Denture bases

Technological Characteristics

VITA Akzent® LC provides a light cured glaze system similar to the predicate device formulas. The composition of the VITA Akzent®LC and the predicates are based on similar materials, therefore this difference does not impact the substantial equivalence.

Non-Clinical Performance Testing

VITA Akzent® LC meets the applicable requirements of the following FDA recognized standards:

- ISO 10993-1:2009 – Biological evaluation of medical devices
- ISO 7405:2004 – Dentistry – Evaluation of biocompatibility of medical devices

Biocompatibility

A biocompatibility assessment was performed on VITA Akzent® AC 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 Akzent® LC is biocompatible and concludes that the device is substantially equivalent to the predicate device in terms of biocompatibility.

Clinical Performance Data

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

Comparison to Predicate Devices

Below is a table showing the predicate device comparison.

	Subject Device	Primary Predicate Device	Reference Device
Device Name	VITA Akzent® LC – K211854	Vident's VITA Enamic Stains– K123761	GC America's Optiglaze – K133836
Device Classification	Coating, Filling Material, Resin	Coating,Filling Material, Resin	Coating,Filling Material, Resin
Product Code	EBD	EBD	EBD
Indication for use	VITA AKZENT LC Indication range: • Restorations made of hybrid ceramic • Restorations made of light curing veneering material • Restorations made of CAD/CAM Composites • Prefabricated Teeth • Denture bases	VITA Enamic Stains are indicated for shade customization and characterization of the surface of dental restorations made of hybrid ceramic-resin and resin materials.	For characterization of direct and indirect composite restorations, acrylic denture base and artificial acrylic teeth. For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.
Technological Characteristics	Liquid	Powder and Liquid	Liquid
Principle of operation	For characterization and glazing restorations	For characterization and glazing restorations	For characterization and glazing restorations
Material composition	A mixture of	A mixture of	Multifuctional acrylate,

	methacrylates, initiators and other non-hazardous additions	methacrylates, initiators and other non-hazardous additions	methyl methacrylate, silica filler, photo initiator, pigment

Differences between Subject and Predicate Devices

The predicate device indication for use was submitted with a more generic indication. Below is how the predicate device is similar in indications for Akzent LC.

The predicate device was designed states that it's intended for customization and characterization of the surface of dental restorations made of hybrid ceramic-resin and resin materials. These terms are similar to the subject's device indication of Restorations made of hybrid ceramic, light-curing veneering material (resin materials), CAD/CAM composites (resin materials) and Denture bases (resin materials)

Both cover the same indications, and no additional indications are added to the subject device, therefore this does not affect the substantial equivalence or efficacy and safety.

The reference device was used since the subject device product is in liquid form as is the reference device. The primary predicate uses a liquid and a powder form. The same mechanism is used, and the subject device is considered a subset of the primary predicate device and equivalent to the reference device. Performance and biocompatibility testing prove that the subject device, in a liquid form, does not impact the safety and effectiveness of the product and shows. The adhesion performance testing conducted against the reference device, shows a more favorable efficacy during bench testing.

Conclusion

Based on the above comparative tables, it is concluded that VITA Akzent®LC is equivalent to the predicate device. VITA Akzent® LC has similar indications for use and similar material composition as the predicate devices.