July 21, 2020

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: K193434
Trade/Device Name: Vita Lumex Ac
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 21, 2020
Received: April 23, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193434

Device Name
VITA Lumex® AC

Indications for Use *(Describe)*
VITA Lumex® AC is used to veneer the following:
• Full and partial veneering of zirconia
• Full and partial veneering of lithium disilicate
• Partial veneering of feldspar ceramic
• Reconstruction without a substructure

Materials:
• Zirconia substructures (CTE approx. 10.0 to 10.5 x 10-6 K-1)
• Glass-ceramic substructures (CTE approx. 9.0 to 10.5 x 10-6 K-1)

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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510(k) Summary

Submitter	VITA Zahnfabrik H.Rauter GmbH Co. Spitelgasse 3 Bad Sackingen, D-79713 Germany Establishment Reg. No. 1000625496
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Official Correspondent	Lindsay Tilton Regulatory Affairs & Compliance Manager VITA North America, Inc. 22705 Savi Ranch Parkway, Suite 100 Yorba Linda, CA 92887 Establishment Reg. No. 2082832 Phone (925)699-9091 Fax (714) 221-6759 E-mail: ltilton@vitanorthamerica.com
Date Prepared	July 15, 2020

- **Trade/Device Name** **Vita** Lumex® AC
- **Classification Name** Porcelain powder for clinical use
- **Regulation Number** 21 CFR 872.6660
- **Product Code** EIH

Predicate Devices

Vident's VITA VM Porcelains– K060441 – *Primary Predicate Device*

Device Description

VITA Lumex® AC is a natural low-fusing veneering ceramic system that is suitable for veneering all ceramic substructures. VITA LUMEX AC standard layering consists of the two Materials DENTINE and ENAMEL. The color-bearing DENTINE materials, which provide good coverage, offer the perfect precondition for the preparation of veneers with intensive shades. With this two-layer alternative, VITA offers an ideal solution for the reproduction of optimal shade results in case of thin walls. Additionally, the intensive shade effect of the DENTINE permits a more generous use of the ENAMEL materials, which create the desired translucency. The user is able to prepare a natural restoration with a lifelike appearance with only two layers. This product is provided non-sterile in glass jars in a powder form to be used in conjunction with the Vita low fusing liquid.

Indications for Use

VITA Lumex® AC is used to veneer the following:

• Full and partial veneering of zirconia

• Full and partial veneering of lithium disilicate

• Partial veneering of feldspar ceramic

• Reconstruction without a substructure

Materials:

• Zirconia substructures (CTE approx. 10.0 to 10.5 x 10-6 K-1)

• Glass-ceramic substructures (CTE approx. 9.0 to 10.5 x 10-6 K-1

Technological Characteristics

VITA Lumex® AC provides a lower fusing veneering ceramic similar to the predicate device formula.

The composition of the VITA Lumex®AC and the predicates are based on similar materials, therefore this difference does not impact the substantial equivalence.

Non-Clinical Performance Testing

VITA Lumex® AC meets the applicable requirements of the following FDA recognized standards:

- DIN EN ISO 6872 2015 - Dentistry – Ceramic Materials
- ISO 10993-1:2009 – Biological evaluation of medical devices
- ISO 7405:2004 – Dentistry – Evaluation of biocompatibility of medical devices

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

Biocompatibility

A biocompatibility assessment was performed on VITA Lumex® 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 Lumex® AC 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 Lumex® AC.

Comparison to Predicate Devices

	Subject Device	Primary Predicate Device
Device Name	VITA Lumex® AC	Vident's VITA VM Porcelains– K060441
Device Classification	Porcelain powder for clinical use	Porcelain powder for clinical use
Product Code	EIH	EIH
Indication for use	VITA Lumex® AC is used to veneer the following: • Full and partial veneering of zirconia • Full and partial veneering of lithium disilicate	Vita VM® porcelains are indicated for use as a veneering material for fixed prosthesis in crowns, bridges, and dental implant abutments. These devices are used in prosthetic dentistry

	• Partial veneering of feldspar ceramic • Reconstruction without a substructure Materials: • Zirconia substructures (CTE approx. 10.0 to 10.5 x 10-6 K-1) • Glass-ceramic substructures (CTE approx. 9.0 to 10.5 x 10-6 K-1)	by forming a porcelain veneer on to a ceramic or metal substructure into the shape of a dental crown.
Components	Powder and Liquid	Powder and Liquid
Principle of operation	for the fabrication of restorations	for the fabrication of restorations

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

The predicate device was designed as a high-fusing, fine-structure feldspar ceramic for Zr02 substructures partially stabilized with yttrium in the CTE range of approx. 10.5.
The predicate's Low-melting materials in eight different shades based on the fine-structure veneering ceramic. They are especially used for individualizing substructure-free restorations made.
The predicate was designed as a high-fusing, fine-structure feldspar ceramic for VITA Glass Ceramic in CET range approx. 12.3 mixed with VITA Low Fusing Modelling liquid

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

Conclusion

Information provided in this application demonstrates that the differences between VITA Lumex®AC and predicate devices do not affect safety and effectiveness, therefore VITA Lumex®AC is substantially equivalent to the predicate devices.