February 23, 2026

Vita Zahnfabrik H. Rauter Gmbh & Co. Kg.
Lindsay Tilton
Regulatory Affairs Consultant
Spitalgasse 3
Bad Sackingen
Baden-Wurttemberg, DE D-79713
GERMANY

Re: K251587
Trade/Device Name: VITA VMLC Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: January 20, 2026
Received: January 20, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251587

Please provide the device trade name(s).

VITA VMLC Primer

Please provide your Indications for Use below.

• Adhesive bonding of metal substructure surfaces (non-precious metal alloys, PM alloys, titanium) with (meth-)acrylate-based resins/composites
• Adhesive bonding of ZrO2 substructure surfaces with (meth-)acrylate-based resins/composites
• Adhesive bonding of cross-linked composites/resins such as VITA CAD Temp or of high-performance polymers (PEEK, PEKK) with (meth-) acrylate-based resins/composites

Please select the types of uses (select one or both, as applicable).

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

510(k) SUMMARY

(21 CFR 807.92)

Submitter: VITA ZAHNFABRIK H. RAUTER GMBH & CO. KG.
Address: SPITALGASSE 3 BAD SACKINGEN Baden – Wurttemberg DE D – 79713 Germany
Contact Person: Mrs. Lindsay Tilton
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Email: ltilton@vitanorthamerica. com
Date Prepared: February 19, 2026

Device Name
Trade Name: VITA VM LC Primer
Common Name: Resin tooth bonding agent
Classification Name: Agent, Tooth Bonding, Resin
Regulation Number: 21 CFR 872.3200
Product Code: KLE
Class: II

Predicate Devices
Primary predicate: Kuraray Alloy Primer (K974089)
Secondary predicate: Signum Universal Bond (K240660)

Device Description
VITA VM LC Primer is a two-component dental bonding system (Primer I and Primer II) used to promote adhesion between dental prosthetic substructures and light-curing (meth)acrylate-based composite veneering resins. Primer I contains functional monomers in a solvent carrier for interaction with substrate surfaces; Primer II is a light-curable methacrylate resin layer that polymerizes using standard dental laboratory light-curing units. The device is supplied as a two-bottle system for sequential application.

Intended Use / Indications for Use
• Adhesive bonding of metal substructure surfaces (non-precious metal alloys, PM alloys, titanium) with (meth-)acrylate-based resins/composites
• Adhesive bonding of ZrO2 substructure surfaces with (meth-)acrylate-based resins/composites
• Adhesive bonding of cross-linked composites/resins such as VITA CAD Temp or of high-performance polymers (PEEK, PEKK) with (meth-) acrylate-based resins/composites

Technological Comparison
The subject and predicate devices use functional monomer-based chemical coupling to promote bonding between prosthetic substrates and methacrylate resin materials. The subject device uses a two-component, sequential application approach including a light-

curable component; these differences do not alter the intended use and do not raise new or different questions of safety or effectiveness.

Performance Data
Non-clinical bench testing was performed in accordance with ISO 10477 (including thermal cycling) and demonstrated adequate bond strength across the indicated substrate materials. Biocompatibility was evaluated in accordance with FDA's *Guidance "Use of International Standard ISO 10993-1,* Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and ISO 7405,* Dentistry — Evaluation of biocompatibility of medical devices used in dentistry. Clinical testing was not performed.

Conclusion
Based on the intended use, technological characteristics, and non-clinical performance and biocompatibility data, VITA VM LC Primer is substantially equivalent to the identified predicate devices.