May 14, 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: K193436
Trade/Device Name: VITA Ambria®
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 10, 2020
Received: February 14, 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)*
K193436

Device Name
VITA Ambria®

Indications for Use *(Describe)*
VITA AMBRIA are zirconia-reinforced lithium silicate press pellets for the fabrication of restorations in the press technique.

Indications

•Occlusal veneers (table tops), veneers
•Inlays, onlays, partial crowns
•Crowns in the anterior and posterior areas
•3-unit anterior bridges up to the second premolar
•Single tooth restorations as implant suprastructures for anterior and posterior teeth
•3-unit bridges as implant suprastructures up to the second premolar
•Single tooth mesostructures in the anterior and posterior areas
•Abutment crowns in the anterior and posterior areas

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary


| | |
|---|---|
| **Submitter** | VITA Zahnfabrik H.Rauter GmbH Co.<br>Spitelgasse 3<br>Bad Sackingen, D-79713<br>Germany<br>Establishment Reg. No. 1000625496 |
| **Contact** | Bernd Walker<br>Head of Regulatory Affairs and Quality Systems<br>Phone (+49) 7761 562-361<br>Fax (+49) 7761 562-384<br>B.Walker@vita-zahnfabrik.com |
| **Official Correspondent** | Lindsay Tilton<br>Regulatory Affairs & Compliance Consultant<br>VITA North America, Inc.<br>22705 Savi Ranch Parkway, Suite 100<br>Yorba Linda, CA 92887<br>Establishment Reg. No. 2082832<br>Phone (925)699-9091<br>Fax (714) 221-6759<br>E-mail: ltilton@vitanorthamerica.com |
| **Date Prepared** | May 11, 2020 |


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

**Predicate Devices**

VITA PM7; PM9 - K050362 – *Primary Predicate Device*

**Device Description**

VITA Ambria® VITA AMBRIA are zirconia-reinforced lithium silicate press pellets for the fabrication of restorations in the press technique.
VITA Ambria comes in various shades and is packaged in a plastic case of 5 or 3 pc pellets. Below are all the available shades:

| | |
|---|---|
| LAM030S0365 | VITA AMBRIA®, A1-T, S, 5 pcs. |
| LAM030S0375 | VITA AMBRIA®, A2-T, S, 5 pcs. |
| LAM030S0385 | VITA AMBRIA®, A3-T, S, 5 pcs. |
| LAM030S0415 | VITA AMBRIA®, B1-T, S, 5 pcs. |
| LAM030S0425 | VITA AMBRIA®, B2-T, S, 5 pcs. |
| LAM030S0465 | VITA AMBRIA®, C2-T, S, 5 pcs. |
| LAM030S0495 | VITA AMBRIA®, D2-T, S, 5 pcs. |
| LAM040S0365 | VITA AMBRIA®, A1-HT, S, 5 pcs. |
| LAM040S0375 | VITA AMBRIA®, A2-HT, S, 5 pcs. |
| LAM040S0385 | VITA AMBRIA®, A3-HT, S, 5 pcs. |
| LAM040S0415 | VITA AMBRIA®, B1-HT, S, 5 pcs. |
| LAM040S0425 | VITA AMBRIA®, B2-HT, S, 5 pcs. |
| LAM040S0465 | VITA AMBRIA®, C2-HT, S, 5 pcs. |
| LAM040S0495 | VITA AMBRIA®, D2-HT, S, 5 pcs. |
| LAM030L0363 | VITA AMBRIA®, A1-T, L, 3 pcs. |
| LAM030L0373 | VITA AMBRIA®, A2-T, L, 3 pcs. |
| LAM030L0383 | VITA AMBRIA®, A3-T, L, 3 pcs. |
| LAM030L0413 | VITA AMBRIA®, B1-T, L, 3 pcs. |
| LAM030L0423 | VITA AMBRIA®, B2-T, L, 3 pcs. |
| LAM030L0463 | VITA AMBRIA®, C2-T, L, 3 pcs. |
| LAM030L0493 | VITA AMBRIA®, D2-T, L, 3 pcs. |
| LAM040L0363 | VITA AMBRIA®, A1-HT, L, 3 pcs. |
| LAM040L0373 | VITA AMBRIA®, A2-HT, L, 3 pcs. |
| LAM040L0383 | VITA AMBRIA®, A3-HT, L, 3 pcs. |
| LAM040L0413 | VITA AMBRIA®, B1-HT, L, 3 pcs. |
| LAM040L0423 | VITA AMBRIA®, B2-HT, L, 3 pcs. |
| LAM040L0463 | VITA AMBRIA®, C2-HT, L, 3 pcs. |
| LAM040L0493 | VITA AMBRIA®, D2-HT, L, 3 pcs. |
| LAM030S0025 | VITA AMBRIA®, 0M1-T, S, 5 pcs. |
| LAM030S0045 | VITA AMBRIA®, 0M3-T, S, 5 pcs. |
| LAM040S0025 | VITA AMBRIA®, 0M1-HT, S, 5 pcs. |
| LAM040S0045 | VITA AMBRIA®, 0M3-HT, S, 5 pcs. |

| | |
|---|---|
| LAM030L0023 | VITA AMBRIA®, 0M1-T, L, 3 pcs. |
| LAM030L0043 | VITA AMBRIA®, 0M3-T, L, 3 pcs. |
| LAM040L0023 | VITA AMBRIA®, 0M1-HT, L, 3 pcs. |
| LAM040L0043 | VITA AMBRIA®, 0M3-HT, L, 3 pcs. |
| LAMSKC | VITA AMBRIA® STARTER KIT VITA classical A1-D4® |

**Statement of Intended Use**

VITA AMBRIA are zirconia-reinforced lithium silicate press pellets for the fabrication of restorations in the press technique.

**Indications**

- Occlusal veneers (table tops), veneers
- Inlays, onlays, partial crowns
- Crowns in the anterior and posterior areas
- 3-unit anterior bridges up to the second premolar
- Single tooth restorations as implant suprastructures for anterior and posterior teeth
- 3-unit bridges as implant suprastructures up to the second premolar
- Single tooth mesostructures in the anterior and posterior areas
- Abutment crowns in the anterior and posterior areas

**Technological Characteristics**

VITA Ambria contains the above components in an insoluble glass matrix similar to VITA PM9 that is used to fabricate restorations in the press technique.

**Non-Clinical Performance Testing**

VITA Ambria® 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 Ambria® is substantially equivalent to the predicate device for its intended use.

**Biocompatibility**

A biocompatibility assessment was performed on VITA Ambria® 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 Ambria® is biocompatible and concludes that the device is safe for its intended use.

**Clinical Performance Data**

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

## Table Comparison to Predicate Devices

| | Subject Device | Primary Predicate Device |
|---|---|---|
| Device Name | **VITA Ambria® AC** | **VITA PM** |
| Device Classification | Porcelain Powder For Clinical Use | Porcelain Powder For Clinical Use |
| Product Code | EIH | EIH |
| Regulation Number | 21 CFR 872.6660 | 21 CFR 872.6660 |
| Indication for use | •Occlusal veneers (table tops), veneers<br>•Inlays, onlays, partial crowns<br>•Crowns in the anterior and posterior areas<br>•3-unit anterior bridges up to the second premolar<br>•Single tooth restorations as implant suprastructures for anterior and posterior teeth<br>•Single tooth mesostructures in the anterior and posterior areas<br>•Abutment crowns in the anterior and posterior areas | o Single and multi-surface inlays<br>o Onlays<br>o Veneers<br>o Partial crowns<br>o Anterior crowns o Premolar crowns<br><br>Also for oxide-ceramic crown and bridge substructures to be veneered with conventional porcelain. |

| | | |
|---|---|---|
| Components | Lithium silicate | Lithium silicate |
| Technology comparison | Pellets in various shades | Pellets in various shades |
| Sterile | Non Sterile | Non Sterile |
| Principle of operation | for the fabrication of restorations in the press technique | for the fabrication of restorations in the press technique |
| Performance Testing | Complies to ISO 6872 | Complies to ISO 6872 |
| Biocompatibility Testing | Complies to ISO 10993-1 | Complies to ISO 10993-1 |

The indications for use are more detailed for the Ambria device, but cover the same indications for the predicate. The indication of the predicate is comparable to that of the new device, even if it is written in a very general way. The subject device lists out all the different substrates it can be used with, while the predicate leaves the terms more general. 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 VITA Ambria® is substantially equivalent to the legally marketed predicate device.