February 21, 2025

Vita Zahnfabrik H.Rauter GmbH & Co.
Lindsay Tilton
Regulatory Affairs Consultant
Spitelgasse 3
Bad Sackingen, : D-79713
GERMANY

Re: K243940
Trade/Device Name: VITA YZ Multi Translucent
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 30, 2024
Received: December 20, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243940

Device Name

VITA YZ MULTI TRANSLUCENT

Indications for Use *(Describe)*

VITA YZ MULTI TRANSLUCENT is indicated for:
• fully anatomical anterior and posterior crowns
• fully anatomical 4 unit anterior and posterior bridges
• fully and partially veneered single tooth and up to 4-unit bridge substructures in the anterior and posterior tooth regions
• inlays
• Onlays
• veneers

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) #: K243940

510(k) Summary

Prepared on: 2025-02-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vita Zahnfabrik H.Rauter GmbH & Co.
Applicant Address	Spitelgasse 3 Bad Sackingen : D-79713 Germany
Applicant Contact Telephone	9256999091
Applicant Contact	Mrs. Lindsay Tilton
Applicant Contact Email	ltilton@vitanorthamerica.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VITA YZ MULTI TRANSLUCENT
Common Name	Porcelain powder for clinical use
Classification Name	Powder, Porcelain
Regulation Number	872.6660
Product Code(s)	EIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180703	VITA YZ ST	EIH
K122269	VITA Enamic	EIH

Device Description Summary

21 CFR 807.92(a)(4)

VITA YZ MULTI TRANSLUCENT are zirconia blanks for reliable shade reproduction. They can be used for the production of fully and partially veneered reconstructions and monolithic bridge restorations in the anterior and posterior tooth regions.
VITA YZ MULTI TRANSLUCENT is part of the VITA YZ SOLUTIONS product group.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

VITA YZ MULTI TRANSLUCENT is indicated for:
- fully anatomical anterior and posterior crowns
- fully anatomical 4 unit anterior and posterior bridges
- fully and partially veneered single tooth and up to 4-unit bridge substructures in the anterior and posterior tooth regions
- inlays
- Onlays
- veneers

Indications for Use Comparison

21 CFR 807.92(a)(5)

1. Differences in Indications for Use
Device Indications for Use
Subject Device (VITA YZ MULTI TRANSLUCENT) - Fully anatomical anterior and posterior crowns

- Fully anatomical 4-unit bridges (anterior and posterior)
- Fully & partially veneered single tooth and up to 4-unit bridge substructures
- Inlays, onlays, veneers
Primary Predicate (VITA YZ ST) - Fully anatomical anterior and posterior crowns
- Multi-unit fully anatomical anterior and posterior bridges (not limited to 4 units)
- Direct screw-retained restorations (crowns & bridges)
- Single-tooth and multi-unit bridge frameworks
Secondary Predicate (VITA Enamic) - Inlays, onlays, veneers, crowns
Key Differences in Indications:
• Subject device vs. primary predicate:
o Subject device is limited to 4-unit bridges, while the primary predicate allows multi-unit bridges.
o Primary predicate supports screw-retained restorations, which the subject device does not.
o Subject device includes inlays, onlays, and veneers, which the primary predicate does not.
• Subject device vs. secondary predicate:
o Subject device covers bridges and veneered structures, whereas Enamic does not.
o Enamic only covers inlays, onlays, veneers, and crowns, making it more similar to lithium disilicate-based materials rather than zirconia frameworks.

Technological Comparison

21 CFR 807.92(a)(6)

Composition Differences:
1. Subject Device (VITA YZ Multi Translucent) vs. Primary Predicate (VITA YZ ST)
o Both are yttria-stabilized zirconia-based materials.
o The subject device has slightly lower aluminum oxide (Al_2O_3) content (0-1%) than the primary predicate (1-3%), improving translucency.
o The primary predicate has higher Al_2O_3, making it stronger but less translucent.
2. Subject Device vs. Secondary Predicate (VITA Enamic)
o The subject device is zirconia-based, while Enamic is silica-based (hybrid ceramic).
o Enamic contains polymer-infiltrated silica, making it more flexible and shock-absorbent.
o Zirconia (subject & primary predicate) is stronger but brittle, while Enamic is more aesthetic and wear-friendly but lacks bridge strength.
Why Composition Matters:
1. Translucency & Aesthetic Use
o The subject device has improved translucency, making it ideal for anterior crowns, veneers, and esthetic restorations.
o The primary predicate is stronger but less translucent, better for large bridges and screw-retained restorations.
o Enamic has the highest translucency but lacks zirconia's strength.
2. Mechanical Strength & Bridge Use
o Subject device: Suitable for 4-unit bridges due to its translucent composition.
o Primary predicate: Supports multi-unit bridges and screw-retained restorations due to higher strength.
o Enamic: Not suitable for bridges due to lower strength.
3. Application Differences
o Subject device: Optimized for high-translucency esthetic restorations and smaller bridges.
o Primary predicate: Optimized for strength, making it suitable for large bridges and screw-retained crowns.
o Secondary predicate (Enamic): Best for veneers, inlays, and onlays due to its flexibility and aesthetics.

Testing Results for VITA YZ MT, YZ ST Color, and YZ ST Multicolor
1. Flexural Strength
o YZ MT (Multi Translucent): 922 ± 95 MPa (meets >800 MPa requirement).
o YZ ST Color: 1073 ± 116 MPa (highest strength).
o YZ ST Multicolor: 1054 ± 95 MPa.
o Conclusion: YZ ST Color had the highest strength, YZ MT had the lowest but still met standards.
2. Linear Coefficient of Thermal Expansion (CTE)
o All materials fall within acceptable ranges:
 YZ MT: 10.4 ×10?^{6} K?^{1}
 YZ ST Color: 10.2 ×10?^{6} K?^{1}
 YZ ST Multicolor: 10.3 ×10?^{6} K?^{1}
3. Chemical Solubility
o YZ MT: 0 µg/cm^2 weight loss (best resistance, no solubility).
o YZ ST Color: 9 µg/cm^2 (below <100 µg/cm^2 requirement).
o YZ ST Multicolor: 10 µg/cm^2.
o Conclusion: YZ MT had the best chemical resistance.
4. Radioactivity & Biocompatibility

o All three met the ≤1.0 Bq/g Uranium 238 limit.

Final Conclusions
• YZ ST Color: Strongest material.
• YZ MT (Multi Translucent): Best translucency and chemical resistance.
• All three materials met thermal expansion, solubility, radioactivity, and biocompatibility standards.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Summary of Non-Clinical Testing Outcomes for VITA YZ ST Multicolor
The VITA YZ ST Multicolor material was tested according to EN ISO 6872 standards for dental ceramic materials. The following key non-clinical tests were performed:

1. Packaging, Marking, and Labeling

Visual inspection confirmed compliance with EN ISO 6872:2019.
No deviations were found in labeling specifications such as brand name, color designation, and lot number.
2. Uniformity

Ensured even distribution of inorganic pigments and organic dyes.
No visible segregation of pigments, meeting EN ISO 6872:2019 requirements.
3. Freedom from Extraneous Materials

Visual inspection confirmed the absence of foreign material.
No contamination was detected in tested samples.
4. Flexural Strength

Measured strength: 1054 ± 95 MPa
Acceptance criteria: Must be greater than 800 MPa
Results exceeded the minimum requirement, confirming the material's durability.
5. Linear Coefficient of Thermal Expansion (CTE)

Measured value: $10.3 \pm 0.1 \times 10?^{6}\ K?^{1}$
Acceptance criteria: Within manufacturer's specified range of $9.8 – 10.8 \times 10?^{6}\ K?^{1}$
Results confirmed compliance with the standard.
6. Chemical Solubility

Measured weight loss: 10 µg/cm²
Acceptance criteria: Must be less than 100 µg/cm²
The material showed minimal solubility, confirming chemical stability.
7. Radioactivity

Tested for uranium-238 activity at Jülich Forschungszentrum.
Measured value: ≤1.0 Bq/g, meeting EN ISO 6872:2019 requirements.
Confirmed safe levels of radioactivity.
8. Biocompatibility

Evaluated according to DIN EN ISO 10993-1 and DIN EN ISO 7405.
Testing verified no adverse biological effects, ensuring safety for clinical use.
Conclusion
The VITA YZ ST Multicolor material successfully met all requirements under EN ISO 6872. It demonstrated high flexural strength, thermal stability, chemical resistance, and biocompatibility, making it suitable for dental applications.