VITA Zahnfabrik H.Rauter GmbH Co.
% Nevine Erian
Director, Regulatory Affairs & Compliance (Consultant)
VITA North America
22705 Savi Ranch Parkway, Suite 100
Yorba Linda, California 92887

August 1, 2018

Re: K180703
Trade/Device Name: VITA YZ ST and VITA YZ XT
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 30, 2018
Received: May 31, 2018

Dear Nevine Erian:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K180703

Device Name

VITA YZ® ST and VITA YZ® XT

Indications for Use *(Describe)*

VITA YZ® ST and VITA YZ® XT materials are blanks used for fabricating dental restorations.

VITA YZ® ST is indicated for fully anatomical anterior and posterior crowns, multi-unit fully anatomical anterior and posterior bridges, fully anatomical crowns and multi-unit bridges on direct screw-retained restorations, and single-tooth and multi-unit bridge frameworks of anterior and posterior crowns and bridges.

VITA YZ® XT is indicated for fully anatomical anterior and posterior crowns, fully anatomical 3-unit anterior and posterior bridges, and anterior and posterior single-tooth and 3-unit bridge frameworks.

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

K180703

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Official Correspondent	Nevine Erian Director, Regulatory Affairs & Compliance (Consultant) VITA North America, Inc. 22705 Savi Ranch Parkway, Suite 100 Yorba Linda, CA 92887 Establishment Reg. No. 2082832 Phone (949) 370-7155 Fax (714) 221-6759 E-mail: nerian@vitanorthamerica.com
Date Prepared	May 29, 2018

- **Trade/Device Name** VITA YZ® ST and VITA YZ® XT
- **Common Name** Zirconia Based , CAD/CAM Material
- **Classification Name** Porcelain powder for clinical use
- **Regulation Number** 21 CFR 872.6660
- **Product Code** EIH

Predicate Devices

VITA In–CERAM YZ Cubes for CEREC® (VITA Zahnfabrik GmbH) – K022996 – ***Primary Predicate***

priti® multidisc Zr02 High Translucent (pritidenta GmbH) – K161025 – ***Reference Predicate***

Device Description

VITA YZ ST and VITA YZ XT discs are pre-sintered zirconia materials, partially stabilized with yttrium oxide (Y-TZP, yttria stabilized tetragonal zirconia polycrystal). VITA YZ ST is made of Super Translucent Zirconia and VITA YZ XT is made of Extra Translucent Zirconia. They offer higher translucency to better match natural dentition.

Statement of Intended Use

VITA YZ® ST and VITA YZ® XT materials are blanks used for fabricating dental restorations.

VITA YZ ST is indicated for fully anatomical anterior and posterior crowns, multi-unit fully anatomical anterior and posterior bridges, fully anatomical crowns and multi-unit bridges on direct screw-retained restorations, and single-tooth and multi-unit bridge frameworks of anterior and posterior crowns and bridges.

VITA YZ XT is indicated for fully anatomical anterior and posterior crowns, fully anatomical 3-unit anterior and posterior bridges, and anterior and posterior single-tooth and 3-unit bridge frameworks.

Material Composition

VITA YZ ST and YZ XT are formulated with yttrium-stabilized zirconia which is identical to the predicate device VITA YZ T (K022996). VITA YZ ST and VITA YZ XT have higher amounts of yttrium, for increased translucency, compared to VITA YZ T.

Technological Characteristics

VITA YZ products are offered in disc and block configurations, in different shades. Blocks have a mandrel attachment, to permit securing into a CAD/CAM machine for milling into a restoration.

Non-Clinical Performance Testing

VITA YZ ST and VITA YZ XT were tested and met the requirements of the following standards:

- ISO 6872:2015 – Dentistry, Ceramic materials
- EN ISO 9693-2:2016 – Dentistry, Compatibility Testing, Ceramic–ceramic systems

Bench test results allowed us to conclude that VITA YZ ST and VITA YZ XT meet their intended use.

Biocompatibility

VITA YZ ST and VITA YZ XT meet biocompatibility requirements of the following standards:

- ISO 10933-1:2009 – B*iological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 7405:2008 Dentistry – *Evaluation of Biocompatibility of Medical Devices Used in Dentistry*

Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of VITA YZ ST and VITA YZ XT.

Substantial Equivalence

Material

VITA YZ ST and YZ XT are similar in chemical composition as the predicate devices.

Physical Properties

VITA YZ ST and YZ XT have similar physical properties as the predicate devices.

Technical Comparison of VITA YZ ST and YZ XT to Predicate Devices

Technical Attribute	**VITA YZ ST and XT**	**VITA IN–CERAM YZ** *(Primary Predicate)*	**priti® multidisc Zr02 HT** *(Reference Predicate)*
Indications			
Fully anatomical anterior and posterior crowns	ST – Yes XT – Yes	Yes	Yes
Multi-unit fully anatomical anterior and posterior bridges	ST – Yes XT – Yes	Yes	Yes
Fully anatomical crowns and multi-unit bridges on direct screw-retained restorations	ST – Yes XT – No	Yes	Yes

Technical Attribute	**VITA YZ ST and XT**	**VITA IN–CERAM YZ** *(Primary Predicate)*	**priti® multidisc Zr02 HT** *(Reference Predicate)*
Single-tooth and multi-unit bridge frameworks of anterior and posterior crowns and bridges.	ST – Yes XT – Yes	Yes	Yes
Fully anatomical 3-unit anterior and posterior bridges	ST – Yes XT – Yes	Yes	Yes
Anterior and posterior single-tooth and 3-unit bridge frameworks	ST – Yes XT – Yes	Yes	Yes
CAD/CAM Material	Yes	Yes	Yes
Physical Configuration	Disc Form	Disc & Block Form	Disc & Block Form
Shades	Different shades	Different shades	Different shades
Meets ISO 6872 Req'ts	Yes	Yes	Yes
Flexural Strength	VITA YZ ST 934 ± 104 MPa VITA YZ XT 678 ± 62 MPa	1165 ± 56 MPa	> 650 MPa

Conclusion

Information provided in this application demonstrates that VITA YZ ST and VITA YZ XT are substantially equivalent in safety and effectiveness to the predicate devices. VITA YZ ST & VITA YZ XT have similar indications for use, similar material composition, similar physical properties, and similar technological characteristics as VITA In–CERAM YZ Cubes for CEREC® and priti® multidisc Zr02 HT. The differences between VITA YZ ST & VITA YZ XT and the predicate devices do not impact safety and effectiveness, as VITA YZ ST & VITA YZ XT share same indications as the predicate devices, meet the same biocompatibility, and ISO 6872 test criteria.