DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Zirkonzahn srl.
Sandra Leitner
Regulatory Affairs Responsible
Via An der Ahr 7
Gais BZ 39030
ITALY

April 4, 2019

Re: K183304
Trade/Device Name: PRETTAU®, ICE and Z-WHITE zirconia blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 11, 2019
Received: January 15, 2019

Dear Sandra Leitner:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.04.04 12:39:07 -04'00'

Enclosure

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

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)*
K183304

Device Name
PRETTAU®, ICE and Z-WHITE zirconia blanks

Indications for Use *(Describe)*
Prettau®, Prettau® 2, Prettau® 2 Coloured, Prettau® 2 Dispersive, ICE Translucent, ICE Premium, ICE Abutment, ICE Translucent Plus, ICE Translucent Plus Coloured, ICE Translucent Plus Dispersive and Z-White are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872.
Prettau® 3, Prettau® 3 Coloured, Prettau® 3 Dispersive, Prettau® 4 Anterior®, Prettau® 4 Anterior® Coloured and Prettau® 4 Anterior® Dispersive are destined for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The products have to be categorized as class 4 according to ISO 6872.
The products have been developed for use with Colour Liquid, ICE Zirkon Ceramics, ICE Zirkon Stains and ICE Zirkon Stains 3D. Observe the relative instructions of use when using these products. The blocks are suitable for all milling units, which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.

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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Section 05
510(k) Summary

510 (k) SUMMARY

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Date Summary Prepared: November 23, 2018

DEVICE IDENTIFICATION

Trade/Proprietary Name:	PRETTAU®, ICE and Z-WHITE zirconia blanks
Generic / Common Name:	Dental zirconia blanks
Regulation Number:	872.6660
Classification Name:	Porcelain powder for clinical use
Class:	II
Product Code:	EIH
Panel:	Dental

LEGALLY MARKETED PREDICATE DEVICE

Company: VITA Zahnfabrik H. Rauter GmbH Co.
Device Name: VITA YZ ST and VITA YZ XT
Product Code: EIH
510(k) Number: K180703

INDICATIONS FOR USE

Prettau®, Prettau® 2, Prettau® 2 Coloured, Prettau® 2 Dispersive, ICE Translucent, ICE Premium, ICE Abutment, ICE Translucent Plus, ICE Translucent Plus Coloured, ICE Translucent Plus Dispersive and Z-White are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872.
Prettau® 3, Prettau® 3 Coloured, Prettau® 3 Dispersive, Prettau® 4 Anterior®, Prettau® 4 Anterior® Coloured and Prettau® 4 Anterior® Dispersive are destined for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The products have to be categorized as class 4 according to ISO 6872.
The products have been developed for use with Colour Liquid, ICE Zirkon Ceramics, ICE Zirkon Stains and ICE Zirkon Stains 3D. Observe the relative instructions of use when using these products. The blocks are suitable for all milling units, which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.

DEVICE DESCRIPTION

The subject devices are composed of yttria-stabilized zirconia. They are available in different models that differ in form and color. The materials used for the submitted devices have a long history of safe use for same or equivalent indications.

DISCUSSION OF NON CLINICAL TESTS

Non clinical testing was performed to determine the physical properties of the subject devices. In consideration of the International Standard ISO 6872 'Dentistry – Polymer-based crown and bridge materials', the devices were tested. All samples fulfil the requirements of the standard.

In consideration of the International Standards 10993-1 'Biological Evaluation of Medical Devices' Part 1: Evaluation and Testing, the subject devices were tested. Biocompatibility testing demonstrated that no issue of biocompatibility arises.

The results of nonclinical tests demonstrate that the devices are equivalent to the predicate devices.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The table below provides a more detailed comparison of the submitted devices and the predicate devices.

Both the Zirkonzahn devices and the predicates are made of yttria-stabilized zirconia that have a well- documented history for use in medical device applications and have been in use for many years.

The submitted devices and the predicates have similar indications for use as well as comparable technical, physical, chemical and biological properties and characteristics.

	PRETTAU®, ICE and Z-WHITE zirconia blanks	**Predicate Device:** **VITA YZ ST and VITA YZ XT K180703**	**Comparison**
Company	ZIRKONZAHN SRL	VITA Zahnfabrik H. Rauter GmbH Co.	
Regulation number	872.6660	872.6660	Same
Product Code	EIH	EIH	Same
Classification name	Porcelain Powder For Clinical Use	Porcelain Powder For Clinical Use	Same
ISO 6872 Class	Class 4 Prettau® 3, Prettau® 4 Anterior Class 5 Prettau®, Prettau® 2, ICE group, Z-White	Class 4 VITA YZ XT Class 5 VITA YZ ST	Same. The indications for use of the new devices as well as of the predicate devices were defined according to the recommended clinical indications in standard ISO 6872:2015. Thus, the indications for use of both are similar.
Composition	Based on yttria-stabilized zirconia	Based on yttria-stabilized zirconia	Similar
Models	Different shades and colors	Different shades and colors	Similar

Intended user	Professional dental technicians	Professional dental technicians	Same
Physical Properties	According to ISO 6872:2015	According to ISO 6872:2015	Same
Flexural Strength	Prettau® 3, Prettau® 4 Anterior: 600 MPa Prettau®, Prettau® 2, ICE group, Z-White : ≥ 900 MPa	VITA YZ XT 678 MPa VITA YZ ST 934 MPa	Similar

CONCLUSION

Based on the available information, the new devices and the predicates are similar in function, composition, production technology and intended use. Therefore, we conclude that the proposed devices are substantially equivalent to the predicates.