DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 8, 2015

Zirkonzahn Gmbh
c/o Mr. Enrico Bisson
Regulatory Senior Consultant
TUV Rheinland Italia S.r.l.
Via della Salute 18/3
Bologna, 40132
ITALY

Re: K151490
Trade/Device Name: Prettau Anterior T0
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: August 28, 2015
Received: September 3, 2015

Dear Mr. Bisson:

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 yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151490

Device Name
PRETTAU® ANTERIOR T0

Indications for Use *(Describe)*
PRETTAU® ANTERIOR T0 is intended to be used for the manufacturing of metal free single-unit anterior and posterior prostheses, inlays, onlays, veneers bonded dental restorations.

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.

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Section 05
510(k) Summary

510 (k) Summary

APPLICANT

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Date Summary Prepared: October 5, 2015

DEVICE IDENTIFICATION

Trade/Proprietary Name: *PRETTAU® ANTERIOR T0*
Generic/ Common Name: Porcelain dental restorative system
Classification name: 21 CFR 872.6660, Porcelain powder for clinical use, Class II
Product Code: EIH
Panel: Dental

LEGALLY MARKETED DEVICE (PREDICATE DEVICE)

ICE Zirkon Transluzen Plus (K132230) by Zirkonzahn Srl

INTENDED USE:

PRETTAU® ANTERIOR T0 is intended to be used for the manufacturing of metal free single-unit anterior and posterior prostheses, inlays, onlays, veneers bonded dental restorations.

DEVICE DESCRIPTION

PRETTAU® ANTERIOR T0 is a millable dental ceramic material made of zirconia.
PRETTAU® ANTERIOR T0 is destined for manufacture with CAD/CAM technology of metal free single-unit anterior and posterior prostheses, implant superstructures, inlays, onlays and veneers as fully anatomical restoration as well as for reduced structures for veneering with ceramics.
The device is compatible with commercially available dental CAD/CAM systems. Such systems must be validated by the user. The blocks are suitable for all milling units which are able to process pre-sintered zirconia and which have the proper clamping device for the corresponding blank. PRETTAU® ANTERIOR T0 is marketed in 25 different outer shapes, i.e. barrel, discs, rectangular, and special shapes; the blocks are produced in various heights from 10mm to 50 mm for each shape.

DISCUSSION OF NON CLINICAL TESTS

In consideration of the International Standard ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, the same tests performed on the predicate device were performed on the final finished subject device to evaluate: In-vitro cytotoxicity, Skin sensitization, Mutagenicity, Irritation. Biocompatibility testing demonstrated that no issue of biocompatibility arises.
Preattau Anterior was tested according to ISO 6872:2008 and is classified as Type II Class a&b and 2a esthetic dental ceramic. The device has been tested for flexural strength, chemical solubility, fracture toughness and CTE.
The results of nonclinical tests demonstrate that the device is equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE

PRETTAU® ANTERIOR T0 equals the predicate device with respect to the indications for use and the fundamental technology, relating to the use of zirconia blocks, the application process (CAD/CAM technology), the biocompatibility and other technical aspects.
The differences in the composition between the new device and the predicate relate to the percentages of yttrium oxide and they have effect on the crystal structure and consequently on the translucency of the device; they have no material effects on the biocompatibility of the device. The composition has not been changed in way that may adversely impact the equivalence with the predicate device.
The PRETTAU® ANTERIOR T0 has a lower mechanical strength than the predicate device (ICE Zirkon Transluzent Plus, 1200 Mpa), due to the fact that the material is completely stabilized with yttrium oxide in order to achieve higher translucency. The resistance to bending is however 600 Mpa, still well above the limits set by ISO 6872:2008.

The section below provides a comparison chart of the submitted device and the predicate devices. Main comparison elements are as follows:

	PRETTAU® ANTERIOR T0 (Submitted Product)	**K132230 - ICE Zirkon Transluzen Plus (Legally Marketed Predicate Device)**
Intended/ Indications For Use	For the manufacturing of single-unit anterior and posterior prostheses, inlays, onlays, veeners bonded dental restorations.	For the fabrication of metal free single and multiple unit crowns/bridges, inlays, onlays bonded dental restorations.
Technology	CAD/CAM fabrication	CAD/CAM and layering ceramic System
Crystal form	cubic	tetragonal
Composition	ZrO_2 residue Y_2O_3 9.35±0.02 Al_2O_3 0.05 ±0.01 SiO_2 <=0.002 Fe_2O3 <0.001 Na_2O -	ZrO2 residue Y2 O3 5.15±0.20 Al2O3 <= 0.1 SiO2 <=0.02 Fe2O3 <0.01 Na2O <0.04
Performance Specifications:		
Flexural Strength (3-pt bend), Mpa	600 Mpa	1200-1400 MPa
Chemical Solubility, microgram/cm^2	<10 µg/cm2	<10 µg/cm2
CTE at 500°C, 10^{-6}/°C	10.1 ± 0.5 x 10^{-6} K^{-1} m/m	9.7 ± 0.5 x 10-6 K-1 m/m
Fracture toughness	1,76	5,9
Glass Transition Temperature (Tg), °C	n.a.	n.a.

Based on the available information, we conclude that the PRETTAU® ANTERIOR T0 is substantially equivalent to the existing legally marketed device under Federal Food, Drug and Cosmetic Act. Therefore, the subject device is determined a to be equivalent to the predicate device.