June 24, 2024

Whitepeaks Dental Solutions GmbH
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K232952
Trade/Device Name: Copran Zri
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 1, 2024
Received: April 2, 2024

Dear Angela Blackwell:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232952

Device Name
Copran Zri

Indications for Use *(Describe)*
Copran Zri consists of machinable zirconia discs for the preparation of full ceramic crowns, onlays and 3-and 4-unit bridges and inlay bridges (anterior and molar.)

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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K232952

Whitepeaks Dental Solutions Copran Zri discs

510K Summary

April 1, 2024

Name and Address: Whitepeaks Dental Solutions GmbH
Alfredstr. 81
45130 Essen Germany
Contact Person: Oliver Puckert
Email: o.puckert@whitepeaks-dental.de
Telephone: +49(281) 206458-11

Name of device: Whitepeaks Dental Solutions Copran Zri discs
Common name: zirconia blanks
Classification Name: Porcelain powder for clinical use
CFR: 21 CFR 872.6660
Primary Product Code: EIH

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
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(704)450-9934
angela@blackwelldevice.com

Device Description:

Pre-sintered zirconia blanks for the fabrication of individual dental restorations.

Copran Zri disks come in both white and pre-shaded light, medium or intense in 95 and 98 mm diameter in thicknesses from 10-25mm.

Indications for Use:

Copran Zri consists of machinable zirconia discs and blocks for the preparation of full ceramic crowns, onlays and 3-and 4-unit bridges and inlay bridges (anterior and molar.)

Testing Summary: The physical properties of Copran Zri were tested according to ISO 6872:2015 and all parameters meet the standard. Testing included bending strength, solubility, radioactivity and thermal expansion coefficient.

A biocompatibility assessment of Copran Zri was done in accordance with ISO 10993-1:2018.

Mechanism of Action: Used in a milling machine for fabrication of a dental restoration

Predicate Device: Ivoclar IPS e.max ZirCad MO K051705

Reference Devices: Whitepeaks Copran Zr K092496

Substantial Equivalence:

The zirconia blanks have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Zirconia discs from Whitepeaks Dental Solutions

Name	Copran Zri	Copran Zri Light, Medium and Intense	Copran Zr Reference Device	Ivoclar ZirCad MO Predicate Device
510k Number	K232952	K232952	K092496	K051705
Common Name	Zirconia blanks	Zirconia blanks	Zirconia blanks	Zirconia blanks
Classification Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Porcelain powder for clinical use	Porcelain powder for clinical use
Class	II	II	II	II
Product Code	EIH	EIH	EIH	EIH
CFR	872.6660	872.6660	872.6660	872.6660
Indications for Use	Copran Zri consists of machinable zirconia discs for the preparation of full ceramic crowns, onlays and 3-and 4-unit bridges and inlay bridges (anterior and molar.)	Copran Zri consists of machinable zirconia discs for the preparation of full ceramic crowns, onlays and 3-and 4-unit bridges and inlay bridges (anterior and molar.)	Copran Zr Zirconia blanks are presintered blanks for CAD CAM or manual milling, made from biocompatible, tetragonal and polycrystalline zirconiumdioxyde. Milling blanks designed for: Crown friameworks in the anterior and posterior areas Bridge frameworks in the anterior and posterior areas Primary conical crowns and telescopic crowns Cantilevered bridges with a max. of one pontic	IPS e.max ZirCAD consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays and 3-and 4-unit bridges and inlay bridges (anterior and molar.)

			having a premolar width Inlays, Onlays, Veneers	
Device Description	Pre-sintered zirconia blanks for the fabrication of individual dental restorations.	Pre-sintered zirconia blanks for the fabrication of individual dental restorations.	Pre-sintered zirconia blanks for the fabrication of individual dental restorations.	Pre-sintered zirconia blanks for the fabrication of individual dental restorations.
Basic Design	Discs	Discs	Discs and blocks	Discs and blocks
Mechanism of Action	Used in a milling machine for fabrication of a dental restoration	Used in a milling machine for fabrication of a dental restoration	Used in a milling machine for fabrication of a dental restoration	Used in a milling machine for fabrication of a dental restoration
Materials	ISO 6872:2015 Type II Class 5	ISO 6872:2015 Type II Class 5	ISO 6872:2015 Type II Class 5	ISO 6872:2015 Type II Class 5
Formula	ZrO_2 with others	ZrO_2 with others	ZrO_2 with others	ZrO_2 with others
Crystal Morphology	Tetragonal	Tetragonal	Tetragonal	Tetragonal
Material	3Y-TZP	3Y-TZP	3Y-TZP	3Y-TZP
Processing	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C
Disc Dimensions	Discs 95mm diameter in thicknesses 10-25mm Discs 98mm diameter in thicknesses 10-25mm	Discs 95mm diameter in thicknesses 10-25mm Discs 98mm diameter in thicknesses 10-25mm	Discs 95mm diameter in thicknesses 10-25mm Discs 98mm diameter in thicknesses 10-25mm	Discs 98mm diameter in thicknesses 10-25mm
Single Use	Yes	Yes	Yes	Yes
Color	None	Pre-shaded	None	Pre-shaded
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Flexural Strength MPa	1400	1400	1400	1150
Fracture Toughness $MPa \cdot m^{1/2}$	5	5	5	>5.1
Solubility $\mu g/cm^2$	6.7	6.7	6.7	<100
CTE (25-500°C) $10^{-6}/K$	10.2	10.2	10.2	10.5 ± 0.5

Radioactivity	< 0.0117 $Bq \cdot g^{-1}$ ^{238}U	< 0.0117 $Bq \cdot g^{-1}$ ^{238}U	< 0.0117 $Bq \cdot g^{-1}$ ^{238}U	Not present in labeling

Conclusion: Copran Zri are substantially equivalent to the predicate device. They have the same indications for use, mechanism of action and similar physical properties and formula. Both the subject devices, the predicate devices and the reference devices physical properties meet ISO 6872:2015. Differences in shapes and sizes between the subject devices and the predicate device are covered by the reference device. Slight differences in diameter do not change their substantial equivalence to the predicate devices as these differences do not change the materials properties in any way, it is just to allow for machine fit.