



September 18, 2024

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

Re: K233064

Trade/Device Name: Copra Supreme
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 19, 2024
Received: June 20, 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.

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,

The logo for the U.S. Food and Drug Administration (FDA) is displayed in a light blue color. It consists of the letters 'FDA' in a bold, sans-serif font. The 'F' and 'D' are connected at the top, and the 'A' is positioned to the right of the 'D'.

Bobak
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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

Indications for Use

510(k) Number (if known)

K233064

Device Name

Copra Supreme

Indications for Use (Describe)

Copra Supreme zirconia blanks are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Whitepeaks Dental Solutions Copra Supreme Zirconia Blanks
510K Summary (K233064)
April 7, 2024

Name and Address: Whitepeaks Dental Solutions GmbH
Alfredstrasse 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 Copra Supreme zirconia blanks
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
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description:

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

Copra Supreme disks come in both white and pre-shaded 0M1-D4 in various sizes.

Indications for Use:

Copra Supreme zirconia blanks are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

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

A biocompatibility assessment of Copra Supreme was done in accordance with ISO 10993-1:2018. Cytotoxicity, irritation, sensitization and genotoxicity were tested and passed.

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

Primary Predicate Device: PrismaTik Dentalcraft Bruxzir Esthetic K213425

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	Copra Supreme white	Copra Supreme OM1-D4	Copran Zr Reference Device	PrismaTik Dentalcraft Bruxzir Esthetic Predicate Device
510k Number			K092496	K213425
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	Copra Supreme zirconia blanks are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.	Copra Supreme zirconia blanks are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.	Copran Zr Zirconia blanks are presintered blanks for CAD CAM or manual milling, made from biocompatible, tetragonal and polycrystalline zirconiumdioxide. Milling blanks designed for: Crown frameworks 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	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

			having a premolar width Inlays, Onlays, Veneers	
Device Description	<p>Pre-sintered zirconia blanks for the fabrication of individual dental restorations.</p> <p>Copra Supreme disks come in both white and pre-shaded 0M1-D4 in various sizes.</p>	<p>Pre-sintered zirconia blanks for the fabrication of individual dental restorations.</p> <p>Copra Supreme disks come in both white and pre-shaded 0M1-D4 in various sizes.</p>	Pre-sintered zirconia blanks for the fabrication of individual dental restorations.	<p>BruxZir® Esthetic blanks are zirconia milling blanks used for the production of esthetic zirconia dental restorations. The high esthetics and high strength of BruxZir® Esthetic restorations make them viable for use in all regions of the mouth. The manufactured dental restorations are made utilizing a CAD/CAM system for design and manufacture. The designed and manufactured dental restorations are then sintered at a high temperature. BruxZir® Esthetic blanks are available in white and pre-shaded</p>

				varieties that can be easily adjusted to match the final shade.
Basic Design	Discs	Discs	Discs and blocks	Discs
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	4Y-TZP	4Y-TZP	3Y-TZP	4Y-TZP
Processing	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C
Dimensions	various	various	various	various
Single Use	Yes	Yes	Yes	Yes
Color	White	Pre-shaded	White	White and Pre-shaded
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Flexural Strength MPa	1100	1100	1400	980
Fracture Toughness MPa·m ^{1/2}	3.5	3.5	5	2.7-3.1
Solubility µg/cm ²	6.8	6.6-6.8	6.7	<100
Radioactivity	< 0.0102 Bq·g ⁻¹ ²³⁸ U	Between <0.0096 and < 0.0170 Bq·g ⁻¹ ²³⁸ U	< 0.0117 Bq·g ⁻¹ ²³⁸ U	No more than 1 Bq·g ⁻¹ ²³⁸ U

Conclusion: Copra Supreme zirconia blanks are substantially equivalent to the predicate device. They have the same indications for use, mechanism of action and similar physical properties and formula. The solubility of the reference device and Copra Supreme are the same when variances in test results are considered as all of them fall between 6.6-6.8. The radioactivity of Copra Supreme is less than that of the reference device so does not impact the substantial equivalence since less radioactivity means less of a safety concern. 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 size and shape do not change their substantial equivalence to the predicate devices.