



June 20, 2024

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

Re: K233158

Trade/Device Name: Copra Smile, Copra Supreme Hyperion
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 21, 2024
Received: May 22, 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

Indications for Use

510(k) Number (if known)

K233158

Device Name

Copra Smile and Copra Supreme Hyperion

Indications for Use (Describe)

Copra Smile consists of machinable zirconia discs and blocks for preparation of single crowns, bridges with maximum of one pontic between two crowns and inlays, onlays and veneers.

Copra Supreme Hyperion 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).

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)

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Whitepeaks Dental Solutions Copra Smile and Copra Supreme Hyperion
510K Summary K233158
September 24, 2023

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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
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Device Description:

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

Copra Smile disks and blocks come in both white and pre-shaded in 0M1, 0M2, 0M3, A1-D4 and Joy Five-Nine in various sizes. Copra Supreme Hyperion disks and blocks come pre-shaded in 0M1, 0M2, 0M3, A1-D4 and Joy Five-Nine in various sizes.

Indications for Use:

Copra Smile consists of machinable zirconia discs and blocks for preparation of single crowns, bridges with maximum of one pontic between two crowns and inlays, onlays and veneers.

Copra Supreme Hyperion 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 Copra Smile and Copra Supreme Hyperion were tested according to ISO 6872:2015 and all parameters meet the standard.

A biocompatibility assessment of Copra Smile and Copra Supreme Hyperion 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: 3M Lava Esthetic K161922

Reference Devices: Ivoclar ZirCad MT K051705

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 and blocks from Whitepeaks Dental Solutions

Name	Copra Smile white	Copra Smile 0M1-D4 Joy Five - Nine	3M Lava Esthetic Predicate Device
510k Number			K161922
Common Name	Zirconia blanks	Zirconia blanks	Zirconia blanks
Classification Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Porcelain powder for clinical use
Class	II	II	II
Product Code	EIH	EIH	EIH
CFR	872.6660	872.6660	872.6660
Indications for Use	Copra Smile consists of machinable zirconia discs and blocks for preparation of single crowns, bridges with maximum of one pontic between two crowns and inlays, onlays and veneers.	Copra Smile consists of machinable zirconia discs and blocks for preparation of single crowns, bridges with maximum of one pontic between two crowns and inlays, onlays and veneers.	Single crowns, bridges with maximum of one pontic between two crowns and inlays, onlays and veneers.
Device Description	Pre-sintered zirconia blanks for the fabrication of individual dental restorations. Copra Smile disks and blocks come in both white and	Pre-sintered zirconia blanks for the fabrication of individual dental restorations. Copra Smile disks and blocks come in both white and	Lava Esthetic zirconia blanks are used for the fabrication of esthetic zirconia restorations. The blanks are available in various heights

	pre-shaded in 0M1, 0M2, 0M3, A1-D4 and Joy Five-Nine in various sizes.	pre-shaded in 0M1, 0M2, 0M3, A1-D4 and Joy Five-Nine in various sizes.	and shades based on the Vita™ Classical shade guide. After sintering, restorations display a gradient shading and inherent fluorescence. The restorations are designed using dental CAD software and the data is converted into milling paths by CAM software. The blanks can be processed in milling units suitable for pre-sintered zirconia. Milled restorations must be final sintered in a furnace suitable for zirconia per the cycle designated for Lava Esthetic.
Basic Design	Discs and blocks	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
Materials	ISO 6872:2015 Type II Class 4	ISO 6872:2015 Type II Class 4	ISO 6872:2015 Type II Class 4
Formula	ZrO ₂ with others	ZrO ₂ with others	ZrO ₂ with others
Crystal Morphology	Tetragonal	Tetragonal	Tetragonal
Material	5Y-TZP	5Y-TZP	5Y-TZP

Processing	Sintering at temperature > 1450°C	Sintering at temperature > 1450°C	Sintering at temperature > 1500°C
Dimensions	various	various	various
Single Use	Yes	Yes	Yes
Color	White	Pre-shaded	White and Pre-shaded
Sterility	Non-sterile	Non-sterile	Non-sterile
Flexural Strength MPa	600-800	600-800	800
Fracture Toughness MPa·m ^{1/2}	3.5	3.5	3-5

Name	Copra Supreme Hyperion 0M1-D4 Joy Five - Nine	Ivoclar ZirCad MT Reference Device
510k Number		K051705
Common Name	Zirconia blanks	Zirconia blanks
Classification Name	Porcelain powder for clinical use	Porcelain powder for clinical use
Class	II	II
Product Code	EIH	EIH
CFR	872.6660	872.6660
Indications for Use	Copra Supreme Hyperion 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.	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.)
Device Description	Pre-sintered zirconia blanks for the fabrication of individual dental restorations. Copra Supreme Hyperion disks	IPS e.max ZirCAD is the material of choice for cases in which high mechanical stability, thin restoration walls and natural-

	and blocks come pre-shaded in OM1, OM2, OM3, A1-D4 and Joy Five-Nine in various sizes.	looking esthetics* are of the essence. Tooth preserving and natural-looking restorations* with considerably reduced wall thicknesses can be created as the material provides high strength.
Basic Design	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
Materials	ISO 6872:2015 Type II Class 5	ISO 6872:2015 Type II Class 5
Formula	ZrO ₂ with others	ZrO ₂ with others
Crystal Morphology	Tetragonal	Tetragonal
Material	4-5Y-TZP	4-5Y-TZP
Processing	Sintering at temperature > 1500°C	Sintering at temperature > 1500°C
Dimensions	various	various
Single Use	Yes	Yes
Color	Pre-shaded	Pre-shaded
Sterility	Non-sterile	Non-sterile
Flexural Strength MPa	600-1100	800
Fracture Toughness MPa·m ^{1/2}	3.5	3-5

Conclusion: Copra Smile and Copra Supreme Hyperion 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. 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.