November 27, 2024

Prevest Denpro Limited
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K233273
Trade/Device Name: C&B Ceramic; C&B Permanent; C&B Interim
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: March 5, 2024
Received: March 6, 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*

k233273

Device Name

C& B Ceramic, C&B Permanent, C&B Interim

Indications for Use *(Describe)*

The C&B Ceramic material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.

The C&B Permanent material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations

C&B Interim material is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral light-curing equipment.

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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C & B Ceramic, C&B Interim, C&B Permanent
510(k) Summary - K233273
November 25, 2024

Name and Address: Prevest Denpro Limited
Unit II, Export Promotion Industrial Park
Bari Brahmana, Jammu 181133 India
Contact Person: Atul Modi
Email: prevestindia@gmail.com
Telephone: (941) 919 4280

Name of device: C&B Ceramic, C&B Interim, C&B Permanent
Classification Name: Tooth shade resin material
CFR: 21 CFR 872.3690
Primary Product Code: EBF
Secondary Product Code: EBG
Regulatory Class: II

Submission Contact:

Angela Blackwell
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Device Description:

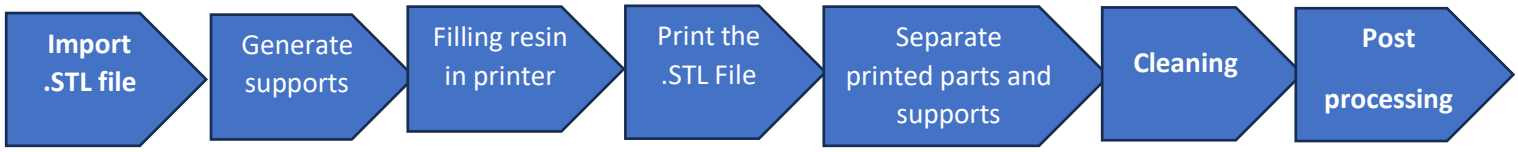
Prevest C&B, Ceramic Resin is a light-curing material with ceramic fillers used for the 3D printing/ fabrication of Ceramic Crown & Bridge dental prosthesis for use in DLP, LCD/MSLA 3D printers. It is reactive to wavelength of light between 385nm and 405nm. Recommended printers and light curing unit are Asiga Max UV, Ackuretta SOL and Acuretta Curie. It is stored in 500 and 1000ml HDPE bottles and is available in several shades: A1 /A2 /A3 /A3.5 /B1 /B2 /B3 /C2 /D3 /Bleach/Extra Bleach based on the shade guide.

Prevest C&B, Interim resin is a light-curing material with glass fillers used for the 3D printing/ fabrication of long term temporary Crown & Bridge dental prosthesis for use in DLP, LCD/MSLA 3D printers. It is reactive to wavelength of light between 385nm and 405nm. Recommended printers and light curing unit are Asiga Max UV, Ackuretta SOL and Acuretta Curie. It is stored in 500 and 1000ml HDPE bottles and is available in several Shades: A1 /A2 /A3 /A3.5 /B1 /B2 /B3/ C2 /D3/Bleach/Extra Bleach based on the shade guide.

Prevest C&B, Permanent resin is a light-curing material with glass fillers for the 3D printing/fabrication of Permanent crown and bride dental prosthesis for use in DLP, LCD/MSLA 3D printers**.** It is reactive to wavelength of light between 385nm and 405nm. Recommended printers and

light curing unit are Asiga Max UV, Ackuretta SOL and Acuretta Curie. It is stored in 500 and 1000ml HDPE bottles and is available in several Shades: A1 / A2 / A3 / A3.5 / B1 / B2 / B3 / C2 / D3/Bleach/Extra Bleach based on the shade guide.

These materials are used for the additive manufacturing of crown and bridge prosthesis following the workflow as depicted below:



Indications for Use:

C&B Ceramic material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.

C&B Permanent material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.

C&B Interim material is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral light-curing equipment.

Testing Summary:

C&B Ceramic, C&B Interim, and C&B Permanent were tested for appearance, flexural strength, sensitivity to ambient light, water absorption, water solubility, color stability, shade stability according to protocols based on ISO 4049 and ISO 10477.

All test results met the criteria in standard.

Shelf life for C&B Ceramic, C&B Interim, and C&B Permanent is 3 years. All shelf life determinations use the same testing protocols as the characterization testing which are based on ISO 4049 and ISO 10477. The predicate and reference devices use the same ISO standard for their testing. Their shelf lives are 2 years, 2,5 years or are not given.

A biocompatibility assessment according to ISO 10993-1 was conducted on all three resins.

Mechanism of Action: 3D printing of dental prosthesis

Type of Printer to Use with the materials: DLP, LCD/MSLA 3D printer with a light spectrum of between 385nm and 405nm like Ackuretta SOLand Asiga Max UV.

Predicate Device: Varseo Crown Plus K201668 and Varseo Smile Temp K193553 from Bego

Reference Devices: Freeprint Temp K200273 from Detax GmbH

Substantial Equivalence:

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

Crown and Bridge Resins for 3D Printing from Prevest Denpro

	C&B Ceramic	C&B Permanent	Varseo Crown Plus K201668 Predicate Device	Freeprint Temp K200273 Reference Device
Product Code	EBF	EBF	EBF	EBG
Indications for Use	C&B Ceramic material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	C&B Permanent material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	Varseo Crown Plus is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile Crown Plus material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	Freeprint Temp is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.
Applicable Standards	ISO 4049 ISO 10477	ISO 4049 ISO 10477	ISO 4049 ISO 10477	ISO 10477
Mechanism of Action	3D printing of dental prosthesis	3D printing of dental prosthesis	3D printing of dental prosthesis	3D printing of dental prosthesis
Composition	Methacrylate polymer resin with photo initiator, inhibitor, UV absorber and pigments	Methacrylate polymer resin with photo initiator, inhibitor, UV absorber and pigments	Methacrylate polymer resin with photo initiator, inhibitor and pigments	Polymer resin with photo initiator, UV absorber and pigments
Flexural Strength ISO 4049 ≥ 100Mpa ISO 10477 ≥50 MPa	>100 MPa	>100 MPa	>100 MPa	>100 MPa
Water Absorption	<40 µg/mm^3	<40 µg/mm^3	<40 µg/mm^3	<40 µg/mm^3

ISO 4049 ≤ 40 µg/mm^3 ISO 10477 ≤ 40 µg/mm^3				
Water Solubility ISO 4049 ≤ 7.5 µg/mm^3 ISO 10477 ≤ 7.5 µg/mm^3	<7.5 µg/mm^3	<7.5 µg/mm^3	<7.5 µg/mm^3	<7.5 µg/mm^3
Shelf Life	3 years	3 years	On label only	2 years

	C&B Interim	Freeprint Temp K200273 Reference Device	VarseoSmile Temp K193553 Predicate Device
Product Code	EBG	EBG	EBG
Indications for Use	C&B Interim material is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral light-curing equipment.	Freeprint Temp is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.	Varseo Temp resin is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral light-curing equipment.
Composition	Polymer resin with photo initiator, UV absorber, filler and pigments	Polymer resin with photo initiator, UV absorber and pigments	Polymer resin, initiator and pigments
Applicable Standards	ISO 4049 ISO 10477	ISO 10477	ISO 4049 ISO 10477
Mechanism of Action	3D printing of dental prosthesis	3D printing of dental prosthesis	3D printing of dental prosthesis
Flexural Strength ISO 4049 ≥ 100Mpa ISO 10477 ≥50 MPa	>100 MPa	>100 MPa	>100 MPa
Water Absorption	<40 µg/mm^3	<40 µg/mm^3	<40 µg/mm^3

ISO 4049 ≤ 40 µg/mm^3 ISO 10477 ≤ 40 µg/mm^3			
Water Solubility ISO 4049 ≤ 7.5 µg/mm^3 ISO 10477 ≤ 7.5 µg/mm^3	<7.5 µg/mm^3	<7.5 µg/mm^3	<7.5 µg/mm^3
Shelf Life	3 years	2 years	On label only

Conclusion: C&B Ceramic, C&B Permanent, and C&B Interim are substantially equivalent to the predicate devices. They have the same indications, similar testing, and very similar ingredients. Both the subject devices and the predicate device have physical parameters which meet requirements of the relevant ISO standards. Shelf life testing is similar to the shelf life testing of predicate or reference device. Reference devices are included to cover any ingredients not covered by the predicate devices. Any differences in ingredients are minor and do not change the substantial equivalence.