November 26, 2024

DentsCare LTDA
% Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
2950 West Cypress Creek Rd. Ste 110
Fort Lauderdale, Florida 33309

Re: K231859
Trade/Device Name: PrimmaArt
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, POW
Dated: September 27, 2024
Received: September 27, 2024

Dear Rodrigo Abreu:

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
ENT Devices
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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)*
K231859

Device Name
PrimmaArt

Indications for Use *(Describe)*
- Fabrication of temporary crowns, bridges, inlays, onlays and veneers;
- Fabrication of long-lasting temporary restorations;
- Rebasing of prefabricated temporary crowns made of composite, polycarbonate or metal.

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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DENTSCARE LTDA
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Ph: 55 - 47 – 3441-6131

K231859

Section 5

510(k) SUMMARY

A) Submitter's Name: DENTSCARE LTDA

Owner / Operator Registration Number: 3007210751

Manufacture Registration Number: 3007210751

B) Address: AV. EDGAR NELSON MEISTER, 474, JOINVILLE, SANTA CATARINA 89219-501 BRAZIL

C) Phone and Fax Numbers

Phone: +55 (47) 34416131

D) Contact Person:

Roberta Uyara

Tel.: +55 (47) 99160-4500

E) Preparation Date: November 25, 2024

F) Classification Name: Crown And Bridge, Temporary, Resin

Common / Usual Name: Temporary crown and bridge resin

Proprietary Name: PrimmaArt

Product Code: EBG

Class: Class II

Regulation: 21 CFR 872.3770

G) Device Description

Self-curing composite that is highly efficient for the production of temporary pieces for indirect dental procedures such as inlays, onlays, crowns, veneers and bridges. The product consists of a base paste and a catalyzing paste stored in a cartridge and in a double-body syringe, from where they are automatically dispensed in the correct proportion (1:1), providing practical clinical procedures with reduced chances of errors or incorporated bubbles.

H) Substantial Equivalence (Predicates):

The PrimmaArt is equivalent with the following product:

Predicate Type	Predicate Description	510(k) Number	Model	Company
Predicate	Main Predicate	K120779	Structur 3	VOCO GmbH
Reference	Biocompatibility Reference	K191306	Llis, Vittra APS	Dentscare LTDA

Reference	Biocompatibility Reference	K201707	Opallis, Opallis Flow	Dentscare LTDA
Reference	Biocompatibility Reference	K183465	Allcem, Allcem Core	Dentscare LTDA

I) Indications for Use Statement:

· Fabrication of temporary crowns, bridges, inlays, onlays and veneers;
· Fabrication of long-lasting temporary restorations;
· Rebasing of prefabricated temporary crowns made of composite, polycarbonate or metal.

Indications for Use Comparison	
PrimmaArt	**Structur 3**
· Fabrication of temporary crowns, bridges, inlays, onlays and veneers; · Fabrication of long-lasting temporary restorations; · Rebasing of prefabricated temporary crowns made of composite, polycarbonate or metal.	- Fabrication of temporary crowns, bridges, inlays, onlays, partial crowns, veneers and temporary posts. - Fabrication of long-term temporary restorations - Rebasing of prefabricated temporary crowns made of composite, polycarbonate or metal.

Discussion:

The products are similar. Both devices are indicated to produce temporary pieces (crowns, bridges, inlays, onlays and veneers), long-term temporary restorations and rebasing of prefabricated temporary crowns made of resin/composite, polycarbonate or metal.

J) Technological Characteristics Comparison:

The predicate device used to establish substantial equivalence for the PrimmaArt device is outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the PrimmaArt to the predicate device stratified by functional modality.

Device Manufacturer and Common Name	**PrimmaArt Dentscare Ltda**	**Structur 3 VOCO GmbH**
510k #	Not assigned yet	K120779
Classification	Class II	Class II
Regulation #	21 CFR 872.3770	21 CFR 872.3770
Product Code	EBG	EBG
Classification Name	Temporary crown and bridge resin	Temporary crown and bridge resin
Patient Population	All the groups	All the groups
Prescription Use	RX only	RX only
Environment	Dental prosthetics and authorized laboratories and clinics. PrimmaArt must be stored in temperatures between 5° to 25°C.	Dental prosthetics and authorized laboratories and clinics. Structur 3 must be stored in temperatures between 4° to 23°C
Applicable Standards	ISO 7491; ISO 10477; ISO 10993; ISO 4049	ISO 7491; ISO 10477; ISO 10993; ISO 4049
Device Sterilization	Not Applicable	Not Applicable
Primary Package Container:	Syringe and cartridge	Syringe and cartridge
Shelf life	2 years	Not disclosed by the manufacturer
Use the same materials or substances in contact with the same human tissues or body fluids?	YES	YES
Is the product in compliance to EN ISO 10993?	YES	YES
Tissues	Enamel and Dentin	Enamel and Dentin
Reusable	NO	NO
Duration	Temporary	Temporary
Part of body	Oral, teeth	Oral, teeth
Is it used for the same clinical condition?	yes	yes

Is it used at the same site in the body?	yes	yes
Is it used in a similar population?	yes	yes
Is it used for the same intended purpose?	yes	yes
Is not foreseen to deliver significantly different performances?	no	no
Is it similar conditions of use?	yes	yes
Is it similar specifications and properties	yes	yes
Is it similar principles of operation?	yes	yes

CLINICAL STEP	**PrimmaArt (Dentscare)**	**Structur 3 (VOCO)**
Two options: total isolation or relative isolation	YES	YES
Application according to adhesive technique	YES	YES
Require finishing and polishing	YES	YES

Specification	**PrimmaArt**	**Structur 3**
Shade consistency and color stability ISO 4049 e 7491	No more than a small color change	Not performed. Not disclosed by the manufacturer.
Setting time and heat released ISO 4049	Setting time: 2m48s Heat released: 0.30 mW/mg	Setting time: 3m02s Heat released: 0.31 mW/mg
Viscosity	Base Paste: 92733 mPa.s Catalyst paste: 90133 mPa.s	Not disclosed by the manufacturer
Surface Finish ISO 10477	According to ISO 10477, the polymerized	Not disclosed by the manufacturer

	composite has a shiny surface	
Radio-opacity ISO 4049	1.68 mm	< 1
Flexing Resistance ISO 10477	65.5 MPa	68.0 MPa
Water sorption and solubility ISO 4049	Sorption: 9.389 ± 1.26 µg/mm^3 Solubility: 1.542 ± 0.32 µg/mm^3	Sorption: 10.527 ± 1.29 µg/mm^3 Solubility: 2.016 ± 0.31 µg/mm^3
Working time	More than 60 seconds	Not disclosed by the manufacturer
Microhardness Vickers	11,81 HV	4,55 HV

Discussion:

The subject device is similar to the predicate device in that they are light activated, usar self-curing, restorative composite, permanently cementing restorations, production of temporary pieces for indirect dental procedures. The subject device and the predicate device have substantially equivalent of indications for use, mode of use, technological properties and fulfil the ISO 7491 e ISO 10477 ISO 4049 minimum requirements. Despite the minor differences in formulation between the subject device and the predicate, they can be considered equivalent, since these differences does not affect the product's laboratorial and clinical performance and safety.

K) Applicable Standards:

In order to reach substantially equivalent to the predicate device the device PrimmaArt was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

ISO 7491:2000 – Dental materials – Determination of colour stability

ISO 10477:2018 – Dentistry – Polymer-based crown and veneering materials

ISO 4049:2009 - Dentistry – Polymer – based, restorative materials

ISO 10993-1 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (EN ISO 10993-1:2009)

L) Non-clinical Testing:

In order to study the performance of the product, pre-clinical tests were performed according to the table below.

Test	Specification	Results
Setting time and heat released	According to EN ISO 4049, for self curing restorative materials, the setting time shall be no more than 5 minutes. The time considered for the project is 2'30" and 3'10" and the heat released less than 0,60mW/mg.	Product was evaluated using the Differential Scanning Calorimetry Test (DSC) and presented results according to the design input.
Viscosity	According to the design input the viscosity of the base and the catalyzer should be between 60000 and 100000 mPa.s.	The test was done using the Brooksfield digital viscosimeter and the results were within the defined limits.
Surface Finish	According to the ISO 10477 standard, the specification for finishing of a surface is that the polymerised composite presents a reflective surface.	It was observed that the surface of the specimen was reflective, so this material is considered to be in accordance with the specifications of the ISO 10477 standard.
Shade consistency and color stability	According to EN ISO 4049 and ISO 7491, acceptance must be made as long as there is no more than a small color change.	Only a small color difference (acceptable according to ISO 4049) was attested, when comparing Sample 3 (color A3) with Bisacrilic Technical Profile FGM. In the other analyzes, no changes were identified.
Radiopacity	According to ISO 4049, the material is considered radiopaque if the specimen has a value of > 1.0 mm, when compared to the aluminum scale, therefore, the value of "X" obtained through the equation of the line, must be > 1.	The FGM Bisacrylic resin, presented results above that specified by ISO 4049.
Flexing Resistance	According to ISO 10477, the specified flexural strength is ≥50MPa.	The FGM Bisacrylic type resin presented all the results within the values specified in the ISO 10477 standard, therefore, the material meets the requirements determined in

		terms of 3-point Flexural Strength.
Water sorption and solubility	According to ISO 4049, the specified for sorption is a maximum of 40 µg/mm³ and for solubility a maximum of 7.5 µg/mm³.	All results below are within the specified limit, therefore the material is considered to conform.
Working time	According to EN ISO 4049, the working time for cementation materials must be at least 60 seconds.	The results show that the product has a working time of more than 60 seconds.
Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage.	The FGM Bisacrylic Resin product did not show significant changes in terms of its physical-chemical properties during the accelerated stability process (225 days).
Evaluation Report of Long-Term Stability (Shelf)	Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results are used to confirm the expiration date and storage conditions.	We don't have any conclusive data about shelf life yet. At the moment we are using the estimated shelf life in 2 years in the storage condition of 25°C, based on no accelerated stability test.
Michohardness Vickers	According to the Project Entry Requirements, the Hardness (HV) must be between 5 and 15 HV, and in the same way, the results must be similar or superior (justified) when compared to the competitor under study.	All results are within the specified limit, so the material is considered as conform.

Conclusion: Based on the performance test applied to this PrimmaArt and the predicate comparison (Structur 3), we conclude that the device in question is substantially equivalent with the predicate, as all products meet the same recognized standards.