October 14, 2021

Dentscare Ltda
% Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
12343 NW 25th St
Coral Springs, Florida 33065

Re: K210231/001
Trade/Device Name: Vittra APS Unique
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 20, 2021
Received: July 21, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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)*
K210231

Device Name
Vittra APS Unique

Indications for Use *(Describe)*
The Vittra APS Unique composite is indicated for use in permanent and deciduous teeth:
- Direct restorations in anterior and posterior teeth (Classes I, II, III, IV, V and VI).

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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510(k) SUMMARY-K210231

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: October 5, 2021

F) Classification Name: Tooth shade resin material.

Common / Usual Name: Tooth shade resin material.

Proprietary Name: Vittra APS Unique

Product Code: EBF

Class: Class II

Regulation: 21 CFR 872.3690

G) Product Description

Light-curing composite for all dental shades for use in anterior and posterior restorations, recommended for all classes of cavities. The composite is radiopaque, with total inorganic load of 72% to 80% in weight (52% to 60% in volume), average particles between 0.8 and 0.9 microns. It does not contain Bis-GMA nor Bis-EMA in its formula, following the present trend of products not made with Bisphenol A (BPA).

The composite has APS as its photoinitiation system. APS stands for Advanced Polymerization System, and consists of a combination of different photoinitiators that interact among themselves amplifying the curing capacity of the light emitted by the light-curing device.

H) Substantial Equivalence:

The Vittra APS Unique is equivalent with the following product:

Equivalence	510(k) Number	Model	Company
Predicate	K191306	Llis, Vittra APS	Dentscare Ltda

I) Intentions for Use:

Indications for Use Comparison	
Vittra APS Unique	**Llis, Vittra APS**
The **Vittra APS Unique** composite is indicated for use in permanent and deciduous teeth: - Direct restorations in anterior and posterior teeth (Classes I, II, III, IV, V and VI).	The **Llis and VITTRA APS** composites are suitable for use in: - Direct restorations in anterior and posterior teeth (I, II, III, IV, V e VI); - Core build-ups; - Teeth splinting; - Indirect restorations such as inlays, onlays and veneers; - Direct veneers with composites; - Restoration of deciduous teeth; - Diastema closing or reduction; - Modification of teeth´s shape (e.g.: conoid teeth); - Cementation of tooth fragments; - Porcelain/composite repairs.

Discussion:

All resin composites can be used for both permanent and deciduous teeth. Furthermore, indications for the new device are within those of the predicate.

J) Technological Characteristics Comparison:

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

Device Manufacturer and Common Name	Vittra APS Unique Dentscare	Llis, Vittra APS Dentscare
510k #	K210231	K191306
Classification	Class II	Class II
Regulation #	21 CFR 872.3690	21 CFR 872.3690
Product Code	EBF	EBF
Classification Name	Tooth shade resin material	Tooth shade resin material
Patient Population	All the groups	All the groups
Prescription Use	RX only	RX only
Environment	Dental prosthetics and authorized laboratories and clinics. Vittra APS Unique must be stored in temperatures between 5° to 30°C	Dental prosthetics and authorized laboratories and clinics. Llis, Vittra APS must be stored in temperatures between 5° to 30°C
Applicable Standards	ISO 4049 ; ISO 10993-1	ISO 4049 ; ISO 10993-1
Device Sterilization	Not Applicable	Not Applicable
Primary Package Container:	Syringe and capsule	Syringe and capsule
Shelf life	3 years	3 years
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	Permanent	Permanent
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	**Vittra APS Unique (Dentscare)**	**LLis, Vitra APS (Dentscare)**
Two options: total dam isolation or relative isolation	YES	YES
Application according to adhesive technique	YES	YES
Size for increments	1.5 mm	1.5-2 mm
Light curing unit	Power: ≥ 450mW/cm^2 Wavelength: 400-500nm	Power: Llis ≥ 450mW/cm^2, Vittra APS 700mW/ cm^2 Wavelength: 400-500nm
Require finishing and polishing	YES	YES

Specification	**Vittra APS Unique**	**Llis**	**Vittra APS**
Sensitivity to ambient light	physically homogeneous	physically homogeneous	physically homogeneous
Depth of cure	4.91 mm	2.44 mm	2.43 mm
Flexural strength	137.8 MPa	138.8 MPa	142.6 MPa
Water sorption and solubility	Sorption: 7.93 µg/mm^3 Solubility: 1.59 µg/mm^3	Sorption: 16.32 µg/mm^3 Solubility: 4.78 µg/mm^3	Sorption: 15.55 µg/mm^3 Solubility: 4.06 µg/mm^3
Radio-opacity	2.23 mm	1.98 mm	2.31mm
Color stability	The observers did not attest any difference of color	The observers did not attest any difference of color	The observers did not attest any difference of color
Tensile Bond	Not requested by ISO 4049		
Shear Bond Strength	Not requested by ISO 4049		

Discussion:
The subject device is similar to the predicate device in that they are light activated, radio-opaque and restorative composite to be used for permanently cementing restorations. The subject device and the predicate device have substantially equivalent of indications for use, mode of use, technological properties and fulfil the EN ISO 4049:2019 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 Vittra APS Unique was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

ISO 4049 - 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)

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Vittra APS Unique demonstrates equivalency to the predicate device.

L) Non-clinical Testing:

In order to study the performance of the product, pre-clinical tests were performed according to the table below, for details about test results please see attachments below.

Test	Specification	Results	Report
Sensitivity to environment lighting – ISO 4049	According to the ISO 4049 standard, acceptance is related to the physical homogeneity of the sample, so the material was compared after the test to the same material pressed between coverslips, but without exposure to ambient light. Thus, there is no difference between the samples.	After to read samples in triplicate, it was found that all samples were presented to be physically homogeneous, thus Vittra APS Unique and the predicate device meet the specifications of the ISO 4049 standard.	
Depth of Cure - ISO 4049	According to ISO 4049, the specified for this material is that its curing depth is: > 1.5 mm.	The results showed that the subject device and predicate device are according the entry requirement related to the depth of cure and the values specified in ISO 4049. Vittra APS Unique: 4.91 mm Llis: 2.44 mm Vittra APS: 2.43 mm	
Colour tone stability after radiation and water absorption - ISO 4049 and ISO 7491	The acceptance must be performed provided that there is no more than a small change in colour, it must be proven as follows: a) comparisons should be made by visual inspection and analysed by three observers with normal vision, who do not identify any differences in	All comparisons were carried out by observers with normal eyesight. They did not attest to any color difference in the samples analysed. The results presented prove that the Vittra APS Unique, Llis and Vittra APS resins are in accordance with products entry requirements as specified in the ISO4049 standard.	

	colour, this comparison must be carried at a distance of 200 to 300 mm for a period of no more than 2 seconds; b) perform the comparison cited in a) in a light chamber at Day Light - D65 mode; c) perform the comparison in paragraph a), by placing the specimen on a diffuse white background of 90% approximate reflectance, and it should have as a limiting size the size of the specimen, which must be surrounded by a grey background with a diffuse reflectance of 30 ± 5%.		
Radiopacity - ISO 4049	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 average results obtained for radiopacity of Vittra Unique APS FGM was 2.23, thus being higher than that specified in ISO 4049. Vittra APS Unique: 2.23 mm Llis: 1.98 mm Vittra APS: 2.31mm	
Flexing Resistance - ISO 4049	According to the ISO 4049 standard the specification for flexural strength is ≥80MPa.	All results below are within the specified limit, so the materials follow ISO 4049. Vittra APS Unique: 137.8 MPa Llis: 138.8 MPa Vittra APS: 142.6 MPa	
Water sorption and solubility.	Sorption: Maximum of 40 μm/mm³.	The results show that Vittra APS Unique and the predicate device products meet the entry	

- ISO 4049	Solubility: maximum of 7.5 µm/mm³.	requirement for sorption and water solubility, in accordance with ISO 4049. Sorption/Solubility (µg/mm^3) Vittra APS Unique: 7.93 / 1.59 Llis: 16.32 / 4.78 Vittra APS: 15.55 / 4.06	
Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage.	Considering the results observed at the end of the 274 days test period, the shelf-life of 3 years in the storage condition of 30 °C for the product can be confirmed.	
Long-term Stability Study	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.	Shelf-life test has not yet been completed, the product is being commercialized based on the results of accelerated stability acquired during the prototype.	

Conclusion: Based on the performance test applied to this Vittra APS Unique and the predicate (Llis, Vittra APS) comparison, we conclude that the subject device is substantially equivalent with the predicates, since all products, meet the same recognized standard.