October 18, 2024

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

Re: K232994
Trade/Device Name: Vittra APS Unique Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: August 20, 2024
Received: August 20, 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
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)*
K232994

Device Name
Vittra APS Unique Flow

Indications for Use *(Describe)*
- Base under direct restorations;
- Small, non-occlusal stress-bearing class I restorations according to minimally invasive filling therapy;
- Pit and fissure sealant;
- Tunnel-type preparation;
- Repair of small enamel defects;
- Bonding of tooth fragments;
- Composite resin repairs;
- Non-carious cervical lesions.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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:**

Paula Cristine de Oliveira

Tel.: +55 (47) 99160-4500

**E) Preparation Date:** August 27, 2024

**F) Classification Name:** Tooth shade resin material.

**Common / Usual Name:** Tooth shade resin material.

**Proprietary Name:** Vittra APS Unique Flow

**Product Code:** EBF

**Secondary product code:** EBC

**Class:** Class II

**Regulation:** 21 CFR 872.3690

**G) Device Description**

Vittra APS Unique Flow is a light-curing composite of low viscosity, with a single shade for all dental shades, suitable for minimally invasive cavity preparations, base/liner and minor repairs. The composite is radiopaque, with a total inorganic filler content of 58% to 62% by weight (56% to 60% by volume) and an average particle size between 1.7 and 1.9 micrometers. It does not contain Bis-GMA or Bis-EMA in its formulation, following the current trend of Bisphenol A (BPA) free products. The composite has the APS as a photoinitiator system, an acronym for Advanced Polymerization System, which consists of a combination of different photoinitiators that interact with each other, amplifying the curing capacity of the light emitted by the by the light-curing units. Added to different materials, the system provides several advantages. APS confers great polymerization power, which allows a greater degree of conversion, obtaining superior stability to ambient light and providing longer working time during restorations.

**H) Substantial Equivalence (Predicate Device):**

The Vittra APS Unique Flow is equivalent with the following product:

| Equivalence | 510(k) Number | Model | Company |
|---|---|---|---|
| Predicate | K201707 | **Opallis Flow** | Dentscare |

## I) Intentions for Use:

| Indications for Use Comparison | |
|---|---|
| **Vittra APS Unique Flow** | **Opallis Flow** |
| - Base under direct restorations;<br>·Small, non-occlusal stress-bearing class I restorations according to minimally invasive filling therapy;<br>- Pit and fissure sealant;<br>- Tunnel-type preparation;<br>- Repair of small enamel defects;<br>- Bonding of tooth fragments;<br>- Composite resin repairs;<br>- Non-carious cervical lesions. | · Base/lining underneath direct restorations;<br>· Small, non-occlusal stress-bearing class I restorations according to minimally invasive filling therapy;<br>· Pit and fissure sealant;<br>· Tunnel-type preparation;<br>· Repair of enamel defects;<br>· Bonding of dental fragments;<br>· Repair in composite resin;<br>· Non-carious cervical lesions;<br>· Planning of preparation walls. |

**Discussion:**

The products are similar. The 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 Flow device is outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Vittra APS Unique Flow to the predicate device.

| Device Manufacturer and Common Name | Vittra APS Unique Flow<br>Dentscare Ltda | Opallis Flow<br>Dentscare Ltda |
|---|---|---|
| **510k #** | Not assigned yet | K201707 |

| | | |
|---|---|---|
| **Classification** | Class II | Class II |
| **Regulation #** | 21 CFR 872.3690 | 21 CFR 872.3690 |
| **Product Code** | EBF, EBC | 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.<br>Vittra APS Unique Flow must be stored in temperatures between 5° to 30°C | Dental prosthetics and authorized laboratories and clinics.<br>Opallis Flow must be stored in temperatures between 5° to 30°C |
| **Applicable Standards** | ISO 7491; ISO 10993 | ISO 7491; ISO 10993 |
| **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** | yes | yes |

| | | |
|---|---|---|
| **population?** | | |
| **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 Flow (Dentscare)** | **Opallis Flow (Dentscare)** |
|---|---|---|
| **Two options: total isolation or relative isolation** | YES | YES |
| **Application according to adhesive technique** | YES | YES |
| **Size for increments** | 1.5 mm | 1.5 mm |
| **Light curing unit** | Power: ≥ 450mW/cm$^2$<br>Wavelength: 400-500nm | Power: ≥ 450mW/cm$^2$<br>Wavelength: 400-500nm |
| **Require finishing and polishing** | YES | YES |

| **Specification** | **Vittra APS Unique Flow (Dentscare)** | **Opallis Flow (Dentscare)** |
|---|---|---|
| **Color stability** | The observers did not attest any difference of color | The observers did not attest any difference of color |
| **Flexural resistance** | 123.8 MPa | 137.80 MPa |
| **Mimicry** | The observers did not attest any difference of color | - |
| **Light Passage** | The applicator is according to the basic requirements regarding the protection of external lighting, being able to provide shelter from light. | - |
| **Depth of Cure** | 3,996 mm | Opaque shades: 2.97 mm<br>Non-opaque shades: 3.01 mm |
| **Radiopacity** | 1,825 mm | 2.49 mm |

| | | |
|---|---|---|
| **Sensitivity to ambient light** | physically homogeneous | physically homogeneous |
| **Water sorption and solubility** | Sorption: 26.834 µg/mm$^3$<br>Solubility: 1.632 µg/mm$^3$ | Sorption: 27.92 µg/mm$^3$<br>Solubility: 5.46 µg/mm$^3$ |
| **Compressive Strength (MPa)** | 338.2 MPa | 339.9 MPa |
| **Elastic Modulus (MPa)** | 5854 MPa | 6836 MPa |
| **Intensity for curing (mW/cm²)** | >450 mW/cm² | >450 mW/cm² |
| **Wavelength for curing (nm)** | 400-500 nm | 400-500 nm |
| **Filler particle size distribuition (µm)** | < 1 micron | < 1 micron |
| **Surface Hardness (HV)** | 53.63 HV | 51.41 HV |
| **Curing time (s)** | 20 s | 40 s |

**SE 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 Flow was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

**ISO 4049:2019** - Dentistry - Polymer-based restorative materials

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

**ISO 10993-1:2018** - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (EN ISO 10993-1:2018)

**EN ISO 10993-3:2003** - Biological evaluation of medical devices - Part 3: Genotoxicity, carcinogenicity and reproductive toxicity.

**ISO 10993-5:2009** - Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity.

**ISO 10993-6:2016** - Biological evaluation of medical devices - Part 6: Test for local effects after implantation.

**ISO 10993-10:2010** - Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitization.

**ISO 10993-11:2006** - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

**EN ISO 10993-18:2020** – Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process.

**Conclusion:**

Based on compliance with the international standard and regulation mentioned above, the device Vittra APS Unique Flow 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 |
|---|---|---|
| **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. | The results presented prove that the Vittra APS Unique Flow FGM resin is according to the product entry requirements, in accordance with the values specified in the ISO4049 standard. |
| **Flexural resistance** | According to the EN ISO 4049 standard, the specification for flexural strength is ≥80MPa. | The results presented prove that the FGM Vittra APS Unique Flow resin is according to the product's entry requirements, being in accordance with the values specified in the ISO4049 standard for 3-point flexural strength.<br><br>*Flexural strength is 123.8 MPa.* |
| **Mimicry** | Acceptance must be made as long as there is no more than a small color difference between the restoration and the model tooth | The results demonstrated that the product meets the specified in the entry requirements regarding mimicry, based on the acceptance criterion mentioned in the ISO 7491 standard and in item 5.3 of the ISO 4049 standard, when shade equivalence is evaluated. |
| **Light Passage** | Stage 1 - The syringe must not allow light to pass through its components when radiation is applied by LED curing light.<br>Stage 2 and 3 - The resin must be removed from the stored location (tube or cap), analyzed sensorially, and show no difference regarding homogeneity, consistency and applicability, when compared to resin without exposure to radiation. | Can conclude that the syringe is according the basic requirements regarding the protection of external lighting, being able to provide shelter from light. |
| **Depth of Cure** | According to ISO 4049, the specified for this material is that its curing depth is: > 1.5 mm. | The results demonstrate that the product meets the entry requirement related to the depth of cure and the values specified in ISO 4049.<br><br>*Depth of Cure: 3,996 mm.* |
| **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 | Vittra APS Unique Flow FGM resin is according to entry requirement for Radiopacity, showing results above that specified by ISO 4049, so the resin can be considered radiopaque. |

| | | |
|---|---|---|
| | the line, must be > 1 | *Radiopacity: 1,825 mm.* |
| **Sensitivity to ambient light** | 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. | The results presented prove that the FGM Vittra APS Unique Flow resin meets the product entry requirements, being in accordance with the values specified in the ISO 4049 standard in terms of sensitivity to ambient lighting. |
| **Water sorption and solubility** | According to EN ISO 4049:<br>Sorption: Maximum of 40 µm/mm³.<br>Solubility: maximum of 7.5 µm/mm³. | The results show that the FGM Vittra APS Unique Flow product meets the entry requirement for sorption and water solubility, in accordance with ISO 4049.<br><br>*Sorption: 26.834 µg/mm³*<br>*Solubility: 1.632 µg/mm³.* |
| **Accelerated Stability Studies** | Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage. | Based on the tests carried out and the results presented over those 274 days, we can guarantee that the Vittra APS Unique Flow product can be marketed for a period of 3 years, provided it is stored within the indicated storage temperature (maximum 30 °C). |
| **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. | The analysis of Shelf Life has not yet been finalized, the product is being commercialized based on the results of accelerated stability acquired during the prototype. |

**Conclusion:** Based on the performance test applied to Vittra APS Unique Flow and the predicate comparison (Opallis Flow), we conclude that the device in question is substantially equivalent with the predicate, as all products meet the same recognized standards.