December 16, 2019

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

Re: K191306
Trade/Device Name: Llis, Vittra APS
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: September 13, 2019
Received: September 17, 2019

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191306

Device Name

Llis and VITTRA APS

Indications for Use *(Describe)*

The Llis and VITTRA APS composite is 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;

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.

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Section 5

510(k) SUMMARY (K191306)

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) 34416131

E) Preparation Date: May 7, 2019

F) Classification Name: Tooth shade resin material.

Common / Usual Name: Tooth shade resin material.

Proprietary Name: Llis, VITTRA APS

Product Code: EBF

Class: Class II

Regulation: 21 CFR 872.3690

G) Device Description

Llis

Llis is a radiopaque composite for anterior and posterior restorations. Its composition was based in modern concepts so that methacrylate monomers, silanes and fillers with adequate size distribution were combined to produce a product with differentiated physical, mechanical and optical properties. Llis presents a simplified shade system, offering enamel, dentin and incisal shades.

Vittra APS

Vittra APS is a highly aesthetic light-curing composite resin recommended for restorations of all classes in anterior and posterior teeth. The composite is radiopaque; its loading particles are composed by spheres of a zirconia complex with average load particle size of 200nm, with total inorganic load of 72% to 82% in weight (52% to 60% in volume). Those characteristics contribute to enhance both mechanical and aesthetic properties, especially evidenced by how easy it is to obtain proper polishing and by the long-lasting surface shining. Vittra APS' formula is free of Bis-GMA and Bis-EMA, following the present trend of products free of Bisphenol A (BPA).

APS is the acronym for Advanced Polymerization System, and it consists of a combination of different photoinitiators that interact among each other amplifying the curing capacity of light emitted from light-curing units. Added to different materials, the system provides different advantages.

In the case of Vittra APS, APS adds as main benefit the reduction or elimination of visual shade and opacity alteration before/after light curing, which enhances the predictability of the result. Another factor is that, although there is very little concentration of camphorquinone - that has a yellowish aspect – APS has great power of polymerization allowing greater degree of conversion. The APS system is activated by any type of light-curing unit available on the market, even those with less power or narrow range of wavelength.

H) Substantial Equivalence:

The Llis, VITTRA APS is equivalent with the following products:

510(k) Number	Model	Company
K183476	3M™ ESPE™ Filtek™ Z250 Universal Restorative	3M COMPANY

I) Intentions for Use:

Intention of Use Comparison	
Llis, VITTRA APS	**3M™ ESPE™ Filtek™ Z250 Universal Restorative**
The **Llis and VITTRA APS** composite is 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;	The **Filtek™ Z250 Universal Restorative** composite is suitable for use in: - Direct anterior and posterior restorations - Core buildups - Splinting - Indirect restorations including inlays, onlays and veneers

Discussion:

The terms found in the intended for use declaration is using different wording, but essentially is intended to similar procedures. Below is the list of terms with its definition showing the substantially equivalence with the predicate device.

- The term "direct veneers with composites": Direct veneers can be included in the "anterior restorations" indications.
- The term "Restoration of deciduous teeth": All resin composites can be used for both permanent or primary teeth.
- The term "Diastema closing or reduction and Modification of teeth's shape": These procedures can be performed with any composite compatible to dental adhesives.
- The term "Cementation of tooth fragments and repairs to porcelain or composite" can be performed with any composite compatible to dental adhesives.

J) Technological Characteristics Comparison:

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

Device Manufacturer and Common Name	**Llis, VITTRA APS Dentscare**	**3M™ Filtek™ Z250 Universal Restorative 3M Company**
510k #	Not assigned yet	K183476
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. Llis, VITTRA APS must be stored in temperatures between 5° to 30°C	Dental prosthetics and authorized laboratories and clinics. 3M™ ESPE™ Filtek™ Z250 Universal Restorative must be stored in temperatures up to 27°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	**LLis and Vitra APS (FGM)**	**Z250 (3M ESPE)**
Two options: total dam isolation or relative isolation	YES	YES
Application according to adhesive technique	YES	YES
Size for increments	1,5-2mm	2-2,5mm
Lightcuring unit	POWER ≥ 450mW/cm2 and WAVELENGTH OF 400-500nm	POWER ≥ 400mW/cm2 and WAVELENGTH OF 400-500nm
Require finishing and polishing	YES	YES

Specification	**Llis**	**Vittra APS**	**Filtek™ Z250 Universal Restorative**
Sensitivity to ambient light	physically homogeneous	physically homogeneous	physically homogeneous

Depth of cure	2.44 mm	2.43 mm	2.39 mm
Flexural strength	138.8 MPa	142.6 MPa	143.8 MPa
Water sorption and solubility	Sorption: 16.32 µg/mm3 Solubility: 4.78 µg/mm3	Sorption: 15.55 µg/mm3 Solubility: 4.06 µg/mm3	Sorption: 15.29 µg/mm3 Solubility: 4.09 µg/mm3
Radio-opacity	1.98 mm	2.31mm	1.94 mm
Color stability	The observers do not attested any difference of color	The observers do not attested any difference of color	The observers do not attested any difference of color
Tensile Bond	Not requested by ISO 4049		
Shear Bond Strength	Not requested by ISO 4049		

Discussion:
The subject devices are 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 devices and the predicate device have substantially equivalent of indications for use, mode of use, technological properties and fulfil the EN ISO 4049:2009 minimum requirements. Despite the minor differences in formulation between the subject devices 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 Llis, VITTRA APS 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 (ENISO 10993-1:2009)

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Llis, VITTRA APS demonstrate 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.

LLIS

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.	All results are within the range specified by ISO 4049.	ATTACHMENT 01 - SENSITIVITY TO ENVIRONMENT LIGHTING
Depth of Cure - ISO 4049	According to ISO 4049, the specification for this material is that its curing depth is: > 1.0 mm for opaque materials and > 1.5 mm for non-opaque materials.	All results are greater than the specified threshold, therefore the material is considered to be in conformity.	ATTACHMENT 02 – DEPTH OF CURE
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 color, 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 color, 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%.	All comparisons were carried out by three observers with normal eyesight (Tiago Vicente, Josley Habinzeureuter and Simone Brasil Carvalho), certified by a competent physician. They did not attest to any color difference in the samples analyzed. The results demonstrate that the product meets ISO 4049.	ATTACHMENT 03 – COLOR TONE STABILITY AFTER RADIATION AND WATER ABSORPTION

Radiopacity - ISO 4049	Compare the individual optical drives of each aluminium scale against the density of each scale (this check must be performed using ISO 4049 as reference). Get the value of the optical density/grey value for the δs thickness of the specimen and determine the corresponding value of aluminium, δa.	The values found in the specimens are between the second and third scale of the aluminum part, proving that the material is radiolucent according to the requirements of ISO 4049	ATTACHMENT 04 – RADIOPACITY
Flexing Resistance - ISO 4049	According to the EN ISO 4049 standard the specification for flexural strength is ≥80MPa.	All results are greater than the specified threshold, therefore the material is considered as conformant.	ATTACHMENT 05 - FLEXING RESISTANCE
Water sorption and solubility. - ISO 4049	Sorption: Maximum of 40 µm/mm³. Solubility: maximum of 7.5 µm/mm³.	The results demonstrate that the product complies the specification in the EN ISO 4049 Standard.	ATTACHMENT 06 - WATER SORPTION AND SOLUBILITY
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.	ATTACHMENT 07 – ACCELERATED STABILITY STUDIES
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.	Considering the results observed at the end of the 36 months of the long-term test (shelf), the shelf life of 3 years in the storage condition of 30°C for the product can be confirmed.	ATTACHMENT 08 – EVALUATION REPORT OF LONG-TERM STABILITY (SHELF)

VITTRA APS

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.	All results are within the range specified by ISO 4049.	ATTACHMENT 09 – SENSITIVITY TO ENVIRONMENT LIGHTING
Depth of Cure - ISO 4049	According to ISO 4049, the specification for this material is that its curing depth is: > 1.0 mm for opaque materials and > 1.5 mm for non-opaque materials.	All results are greater than the specified threshold, therefore the material is considered to be in conformity.	ATTACHMENT 10 – DEPTH OF CURE

Colour tone stability after radiation and water absorption - ISO 4049	The acceptance must be performed provided that there is no more than a small change in color, 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 color, 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%.	All comparisons were carried out by three observers with normal eyesight (Tiago Vicente, Josley Habinzeureuter and Simone Brasil Carvalho), certified by a competent physician. They did not attest to any color difference in the samples analyzed. The results demonstrate that the product meets ISO 4049.	ATTACHMENT 11 – COLOUR TONE STABILITY AFTER RADIATION AND WATER ABSORPTION.
Radiopacity - ISO 4049	Compare the individual optical drives of each aluminium scale against the density of each scale (this check must be performed using ISO 4049 as reference). Get the value of the optical density/grey value for the δs thickness of the specimen and determine the corresponding value of aluminium, δa.	The values found in the specimens are between the second and third scale of the aluminum part, proving that the material is radiolucent according to the requirements of ISO 4049	ATTACHMENT 12 – RADIOPACITY
Flexing Resistance - ISO 4049	According to the EN ISO 4049 standard the specification for flexural strength is ≥80MPa.	All results are greater than the specified threshold, therefore the material is considered as conformant.	ATTACHMENT 13 – FLEXING RESISTANCE
Water sorption and solubility. - ISO 4049	Sorption: Maximum of 40 µm/mm³. Solubility: maximum of 7.5 µm/mm³.	The results demonstrate that the product complies the specification in the EN ISO 4049 Standard.	ATTACHMENT 14 – WATER SORPTION AND SOLUBILITY.
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.	ATTACHMENT 15 – ACCELERATED STABILITY STUDIES
Evaluation Report Of Long-Term Stability	Study designed to verify the physical and chemical characteristics of the	Considering the results observed at the end of the 36	ATTACHMENT 16 – EVALUATION

(Shelf)	product during the expected shelf life. The results are used to confirm the expiration date and storage conditions.	months of the long-term test (shelf), the shelf life of 3 years in the storage condition of 30°C for the product can be confirmed.	REPORT OF LONG-TERM STABILITY (SHELF)
Color change during polymerization – Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	A comparative analysis will be carried out between commercial composites of internationally recognised quality and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a value statistically ≤ than the competing composites analysed.	Vittra APS showed the least change in color, being similar to the resins Estelite Quick (Tokuyama) and Filtek Z350 XT (3M ESPE).	ATTACHMENT 17 – COLOR CHANGE DURING POLYMERIZATION
Knoop hardness Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	A comparative analysis will be carried out between commercial composites of internationally recognised quality and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a value statistically ≥ than the competing composites analysed.	Vittra APS showed greater surface hardness among the composites that participated in the trial, showing surprising values. Such hardness originates in the quality, morphology and content of the loads used as well as in the quality of the polymers formed and its integration with those loads.	ATTACHMENT 18 – KNOOP HARDNESS
Conversion rate Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	A comparative analysis will be carried out between commercial composites of internationally recognised quality and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a value statistically ≥ than the competing composites analysed.	Vittra APS showed a conversion degree statistically equal to the best results of the other materials under analysis and within a considered range. The excellent mechanical results demonstrated are an evidence for that observation.	ATTACHMENT 19 – CONVERSION RATE
Elasticity Module Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	A comparative analysis will be carried out between commercial composites of internationally recognised quality and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a mean equal to or slightly less than that of human dentin (10-15 Gpa).	Vittra APS showed an elasticity module superior to the one of resins Estelite Quick (Tokuyama Dental) and Tetric N-Ceram (Ivoclar Vivadent), being compatible to the lowest limiting value that is attributed to the human dentine.	ATTACHMENT 20 – ELASTICITY MODULE
Compressive Strenght Study carried out at	A comparative analysis will be carried out between commercial composites of internationally recognised quality	It is noticeable that Vittra APS showed compressive strength statistically equal to the best	ATTACHMENT 21 – COMPRESSIVE

Universidade Estadual de Ponta Grossa (UEPG) and *Universidade Federal do Maranhão*	and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a value statistically ≥ than the competing composites analysed.	results of the other materials under analysis.	STRENGHT
Flexural Resistance ISO 4049 Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	According to the EN ISO 4049 standard, the specification for flexural strength is ≥80MPa.	The result shows that Vittra APS has excellent bending resistance, statistically comparable or superior to products already well known in the market.	ATTACHMENT 22 – FLEXURAL RESISTANCE
Roughness before and after simulated brushing. Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	A comparative analysis will be carried out between commercial composites of internationally recognised quality and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a value ≤ than the competing composites analysed.	Vittra APS was the only composite that did not show increase in surface roughness after simulated brushing. The result demonstrates high resistance to abrasion and reflects the properties that were already expected due to the high Knoop Hardness value that the product has. From a practical point of view, it is noticeable that Vittra APS showed an increase in the smoothness of the product, which explains the long lasting maintenance of its shine	ATTACHMENT 23 – ROUGHNESS BEFORE AND AFTER SIMULATED BRUSHING.
Fracture Toughness. Study carried out at *Universidade Estadual de Ponta Grossa (UEPG)* and *Universidade Federal do Maranhão*	A comparative analysis will be carried out between commercial composites of internationally recognised quality and the composite under analysis. It is defined that the acceptance criterion for this test is if the composite under study has a value statistically ≥ than the competing composites analysed.	Vittra APS showed fracture toughness statistically equal to the best results of the other materials under analysis.	ATTACHMENT 24 – FRACTURE TOUGHNESS.

Conclusion: Based on the performance test applied to this Llis, VITTRA APS and the predicate comparison, we conclude that the subject device is substantially equivalent with the predicate.