February 25, 2020

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

Re: K191389
Trade/Device Name: Allcem Veneer APS
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: November 25, 2019
Received: November 27, 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 “Nandu” 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)*
K191389

Device Name
Allcem Veneer APS

Indications for Use *(Describe)*
Allcem Veneer APS is an adhesive luting of ceramic and composite restorations (fabricated at the chair-side or in the laboratory) with a low layer thickness (up to 1.5 mm) that enable the use of a purely light-curing technique due to their high translucency.

Allcem Veneer Try-in accessory is used to simulate the chromatic effect that will be provided when selected the ideal color of Allcem Veneer cement.

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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Ph: 55 - 47 – 3441-6131

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) 34416131
Email: roberta.uyara@fgm.ind.br

E) Date of the most recent revision: February 24, 2020

F) Classification Name: Material, Tooth Shade, Resin

Common / Usual Name: Material, Tooth Shade, Resin

Proprietary Name: Allcem Veneer APS

Product Code: EBF
Class: Class II
Regulation: 21 CFR 872.3690

G) Device Description

ALLCEM VENEER APS

Allcem Veneer APS is a light-curing resin cement for adhesive cementation of no-prep or indirect veneers of up to 1.5mm of thickness, that do not have opaque infrastructure. The cement is presented as a single component (single syringe) and must be used according to the adhesive cementation technique (acid etching + adhesive).
APS is the acronym for Advanced Polymerization System, and it consists of a combination of different photo initiators that interact among each other amplifying the curing capacity of light emitted from light-curing units.

Presentation Form:

- syringe (2,5g) of Allcem Veneer APS cement in shade A1
- syringe (2,5g) of Allcem Veneer APS cement in shade A2
- syringe (2,5g) of Allcem Veneer APS cement in shade A3
- syringe (2,5g) of Allcem Veneer APS cement in shade Trans (Translucent)
- syringe (2,5g) of Allcem Veneer APS cement in shade Opaque
- syringe (2,5g) of Allcem Veneer APS cement in shade White
- syringe (2,5g) of Allcem Veneer APS cement in shades E-Bleach M
- syringes (2g) of Try-in

H) Substantial Equivalence:

The Allcem Veneer APS is equivalent with the following products:

510(k) Number	Model	Company
K142389	Variolink® Esthetic	Ivoclar Vivadent, AG

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I) Indications for Use:

Indications for Use Comparison	
Allcem Veneer APS	**Variolink® Esthetic**
Allcem Veneer APS is an adhesive luting of ceramic and composite restorations (fabricated at the chair-side or in the laboratory) with a low layer thickness (up to 1.5 mm) that enable the use of a purely light-curing technique due to their high translucency. Allcem Veneer Try-in accessory is used to simulate the chromatic effect that will be provided when selected the ideal color of Allcem Veneer cement.	Variolink Esthetic LC: – Permanent adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and composite restorations (inlays, onlays and veneers) - Only use Variolink Esthetic LC for restorations with a low thickness of <2mm that have sufficient translucency (e.g. restorations made of IPS e.max R HT). Variolink Esthetic DC: – Adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and compositemrestorations (inlays, onlays,partial crowns, crowns, bridges). – Restorations made of opaque ceramics, e.g. oxide ceramics, can only be permanently cemented if an adhesive is additionally used that is separately light-cured. Variolink Esthetic Try-In: To evaluate the overall effect of the restoration in conjunction with the various Variolink Esthetic shades prior to permanent cementation.

Allcem Venner APS is a light-cured resin cement for adhesive cementation of ceramic and composite restorations with a low layer thickness (up to 1.5 mm) that does not have an opaque infrastructure. The predicate model that the subject device demonstrates equivalence to is the Variolink Esthetic LC. The Variolink Esthetic LC version has a similar indication of use only for restorations (ceramic and composite) with a low thickness <2mm that have sufficient translucency. The difference between products is the thickness indicated, our product has more restricted range, assuring the high translucency and quality of the procedure. This slight difference that does not impact the substantial equivalence of the subject device, considering all the other similarities.

Regarding the accessory product, both have the same indication of use, that is to simulate the color of the restoration before the use of the permanent cement (Allcem Veneer APS/Variolink Esthetic LC).

J) Technological Characteristics Comparison:

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

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Device Manufacturer and Common Name	**Allcem Veneer APS Dentscare**	**Variolink® Esthetic Ivoclar Vivadent, AG**
510k #	K191389	K142389
Classification	Class II	Class II
Regulation #	21 CFR 872.3690	21 CFR 872.3690
Product Code	EBF	EBF
Classification Name	Material, Tooth Shade, Resin	Material, Tooth Shade, Resin
Patient Population	Adults	Adults
Prescription Use	RX only	RX only
Environment **Storage Environment**	Dental prosthetics and authorized laboratories and clinics. 5° to 25°C	Dental prosthetics and authorized laboratories and clinics. 2-28 °C/36-82 °F
Applicable Standards	ISO 4049 ; ISO 10993-1	ISO 4049 ; ISO 10993-1
Base Composition	Methacrylate Monomers, camphorquinone, co-initiators, pigments, Barium-Aluminum-silicate salinized glass particles and silicon dioxide.	The monomer of Variolink Esthetic is composed of urethane dimethacrylate and further methacrylate monomers. The inorganic fillers are ytterbium trifluoride and spheroid mixed oxide. Initiators, stabilizers and pigments are additional ingredients.
Device Sterilization	Not Applicable	Not Applicable
Primary Package Container :	Syringe	Syringe
Shelf life	2 years	Not declared
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, tooth	Oral, tooth
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
Film Thickness	11.8 µm	22.0 µm
Stability of tone and colour – ISO 4049	The observers do not attest any difference of colour	The observers do not attest any difference of colour
Flexural Strength – ISO 4049	110.90 MPa	91.84 MPa
Depth of Cure– ISO 4049	2.19 mm	1.62 mm
Radiopacity– ISO 4049	2.47 mm	2.36 mm
Sensitivity to environment lighting	Present a Sensitivity to environment lighting superior to the acceptance criteria.	Present a Sensitivity to environment lighting superior to the acceptance criteria.
Water sorption and solubility – ISO 4049	Sorption: 24.46 µg/mm^3 Solubility: 6.17 µg/mm^3	Sorption: 25.61 µg/mm^3 Solubility: 5.27 µg/mm^3

MODE OF USE

CLINICAL STEP	Allcem Veneer APS (DENTSCARE)	Variolink® Esthetic
TWO OPTIONS: TOTAL DAM ISOLATION OR RELATIVE ISOLATION	YES	YES
APPLICATION ACCORDING TO ADHESIVE TECHNIQUE	YES	YES
SIZE FOR INCREMENTS	Up to 1.5mm	Up to 2mm
LIGHTCURING UNIT	POWER ≥ 450mW/cm^2 and WAVELENGTH OF 400-500nm	POWER ≥ 500mW/cm2 and WAVELENGTH OF 400-500nm
REQUIRE FINISHING AND POLISHING	YES	YES

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Substantial Equivalence Discussion:

The subject device is similar to the predicate devices in that they are all resin cement for adhesive cementation of ceramic and composite resin restorations.

Despite differences in comparison, the subject device demonstrates substantial equivalence to the declared predicate, since all products meet ISO 4049 and the results match the requirements of this International Standard and it does not affect the substantial equivalence.

- Film thickness: As the individual results as the average result for film thickness of the subject device are no greater than 50 µm (according to the ISO 4049 standard). The predicate device also meets the ISO 4049, and the subject device shows substantial equivalence to the predicate device.

- Stability of tone and color: Both products do not attest any difference of color, being in accordance to ISO 4049.

- Flexural strength: The average of the results of Allcem Veneer APS is ≥ the average of the predicate device analyzed in the study. By the results obtained, the subject device demonstrates substantial equivalence to the predicate device.

- Depth of cure: The average of the results of Allcem Veneer APS is ≥ the average of the predicate device analyzed in the study. By the results obtained, all the products analyzed presented satisfactory results in accordance to ISO 4049, and the subject device demonstrates substantial equivalence to the predicate device.

- Radiopacity: The average results found for both products are similar, demonstrating similar radiopacity characteristics between products.

- Sensitivity to environment lighting: Both products have demonstrated physical homogeneity when initial samples were compared with samples that were exposed to radiation.

- Water sorption and solubility: The results show that the subject device presented Sorption and Solubility similar to the competing product under analysis.

Conclusion: From the comparison results obtained, the subject device Allcem Venner APS demonstrates equivalence with the predicate device, since both meet ISO 4049 and both have similar technological and intentions for use.

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K) Applicable Standards:

In order to reach substantially equivalent to the predicate device, the device Allcem Veneer 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 (EN ISO 10993-1:2009)

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Allcem Veneer APS demonstrate equivalency to the predicate above, once both products are in compliance to ISO 4049 and there is no statistical difference among the materials, assuring equivalence between the composites.

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 summary below.

<table>
<tr><th>Test</th><th>Specification</th><th>Results</th></tr>
<tr><td>Sensitivity to environment lighting – ISO 4049</td><td>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.</td><td>Present a Sensitivity to environment lighting superior to the acceptance criteria (> 60 sec).</td></tr>
<tr><td>Depth of Cure - ISO 4049</td><td>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.</td><td>All results are greater than the specified threshold, therefore the material is considered to be in conformity.
<table>
<tr><th>Specimen (mm)</th><th>Variolink Veneer</th><th>Allcem Veneer APS</th></tr>
<tr><td>CP 1</td><td>1.63</td><td>2.25</td></tr>
<tr><td>CP 2</td><td>1.61</td><td>2.19</td></tr>
<tr><td>CP 3</td><td>1.63</td><td>2.14</td></tr>
<tr><td>Average:</td><td>1.62</td><td>2.19</td></tr>
</table></td></tr>
</table>

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Color 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 colour, it must be proven as follows: a) comparisons should be made by visual inspection and analyzed by three observers with normal vision, who do not identify any differences in 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%.	All comparisons were carried out by three observers with normal eyesight and certified by a competent physician. Any color difference in the samples analyzed were attested. The results demonstrate that the product meets ISO 4049.
Flexural strength	According to the EN ISO 4049 standard the specification for flexural strength is ≥50MPa.	All results are greater than the specified threshold, therefore the material is considered to be in conformity Allcem Veneer APS: 110.90 MPa Variolink: 91.84 MPa
Film Thickness.	According to the EN ISO 4049 standard the film thickness for cementing material should be less than 50 µm and also should not be 10 µm above any value declared by the manufacturer, so the company FGM - Dentscare does not declare the film thickness of the product in question (Allcem), so the result of acceptance must be less than 50 µm	From the results obtained it is observed that the film thickness is ≤ 40 µm, thus complying with EN ISO 4049. **Allcem Veneer APS** Sample 1: 17 µm Sample 2: 15 µm Sample 3: 13 µm Sample 4: 09 µm Sample 5: 05 µm Average: 11.8 µm **Variolink** Sample 1: 25 µm Sample 2: 18 µm Sample 3: 27 µm Sample 4: 20 µm Sample 5: 20 µm Average: 22.0 µm

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Water sorption and solubility.	Sorption: Maximum of 40 µm/mm³. Solubility: maximum of 7.5 µm/mm³.	The results demonstrate that the Allcem product complies the specification in the EN ISO 4049 Standard. Allcem Veneer APS: Sorption: 24.46 µg/mm^3 Solubility: 6.17 µg/mm^3 Variolink: Sorption: 25.61 µg/mm^3 Solubility: 5.27 µg/mm^3
Radiopacity	The opacity value (equivalent to aluminum) of a specimen with 1.0 mm thickness is given by δa/δss. If this value is ≥ 1 mm, the material will be in accordance with the first requirement where: If the manufacturer declares that the material is radiopaque, the radiopacity must be of a thickness greater than or equal to the aluminum material and should not be 0.5 mm above any value declared by the manufacturer.	The value 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. Allcem Veneer APS: 2.47 mm Variolink: 2.36 mm
Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the ALLCEM VENEER APS product in forced conditions of storage. The study was performed using independent methods and references of the ASTM1980.	Considering the results observed at the end of the 129 days test period, the shelf-life of 2 years in the storage condition of 25 °C for the Allcem product can be confirmed.
Evaluation Report of Long-Term Stability (Shelf)	Study designed to verify the physical and chemical characteristics of the product ALLCEM VENEER APS during the expected shelf life. The results are used to confirm the expiration date and storage conditions. The study was performed using independent methods and references of the ASTM1980.	Based on the results obtained over the 24 months of the study, we can ensure that Allcem Veneer APS maintains its properties in the indicated storage condition for a period of 2 years.

Conclusion: Based on the performance test applied to Allcem Veneer APS and the predicate comparison, we conclude the specified intentions of use for this product was reached as well as the substantially equivalency with the predicate. The products have similar formulation, indication of use and are in comply with ISO 4049. Observing the results above, Allcem Veneer APS shows similar results when compared to the predicate device, Variolink and is substantially equivalent.