November 2, 2019

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

Re: K183465
Trade/Device Name: Allcem, Allcem Core
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: EMA, EBF
Dated: October 1, 2019
Received: October 4, 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,

Srinivas Nandkumar, Ph.D.
Acting 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)*
K183465

Device Name
Allcem and Allcem Core

Indications for Use *(Describe)*
Allcem and Allcem Core are indicated for the cementation of indirect restorations of the tooth structure. It can be used for luting:
· Porcelain fused-to-metal crowns and bridges;
· Metal crowns, bridges, inlays and onlays (high noble, noble, and base metals);
· Crowns and bridges with minimal tooth structure;
· Maryland bridges (resin bonded bridges);
· All ceramic/porcelain and pre-cured composite crowns, bridges, inlays and onlays;
· Endodontic posts;
* Only for Allcem Core: Core build-up.

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

October 2, 2019

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: October 2, 2019

F) Classification Name: Dental cement.

Common / Usual Name: Dental cement

Proprietary Name: ALLCEM and ALLCEM CORE

Product Code: EMA

Class: Class II

Regulation: 21 CFR 872.3275

G) Device Description

ALLCEM

Allcem is a dual-curing radiopaque permanent resin cement system indicated for the cementation of indirect restorations to the tooth structure. The product is composed of a base paste and a catalyst paste, stored in a double-body syringe, which allows releasing the correct proportion of each paste (1:1) and separating syringes of base paste and catalyst paste. Allcem is composed of methacrylate monomers, such as TEGDMA and BisEMA, inorganic load, photoinitiators, coinitiators, catalysts and pigments. Allcem presents adjusted viscosity allowing the formation of fine layers of cement with the appropriate covering of the parts.

ALLCEM CORE

Allcem Core is a dual-curing resin cement specially conceived for the adhesive cementation of intraradicular posts, crowns and core build-up . The product is commercialized in a double-body syringe, which facilitates obtaining the correct

mixing proportions of the two pastes (1:1), and eases clinical procedures. By using an self-mixing tip with an applying nozzle (intracanal tip), it is possible to apply the cement inside the root canal and easily cement the post. The same tip can be used to add material to the crown region of the post to build up the core, Allcem Core is a composite of methacrylate monomers such as BisGMA, BisEMA and TEGDMA, inorganic load, photoinitiators, coinitiators, catalysts and pigments. The cement associates the necessary flow for applications in canals with the ideal thixotropy for core build-ups.

H) Substantial Equivalence:

The ALLCEM and ALLCEM CORE is equivalent with the following product:

510(k) Number	Model	Company
K110508	Suglue-10	3M Espe

I) Reference Device:

510(k) Number	Model	Company
K060893	Rebilda DC	VOCO GMBH

J) Indications for Use:

Indication for Use Comparison		
Allcem and Allcem Core **Dentscare**	**Suglue-10** **3M Espe**	**Rebilda DC** **VOCO**
Allcem and Allcem Core are indicated for the cementation of indirect restorations of the tooth structure. It can be used for luting: · Porcelain fused-to-metal crowns and bridges; · Metal crowns, bridges, inlays and onlays (high noble, noble, and base metals); · Crowns and bridges with minimal tooth structure; · Maryland bridges (resin bonded bridges); · All ceramic/porcelain and pre-cured composite crowns, bridges, inlays and onlays; · Endodontic posts; * Only for Allcem Core: Core build-up.	Final cementing of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis) - Final cementing of posts and screws - Final cementation of all-ceramic, or composite veneers - Final cementation of all-ceramic, composite, or metal restorations on implant abutments	Rebilda DC is a dual-curing, radiopaque, flowable composite indicated for core build-ups of vital and non-vital teeth.

Discussion: The subject devices and predicate device have the same indication, are cements indicated for cementing intra-radicular pins and indirect restorations (bridges, crowns, inlays, onlays and facets).

Both can be used with the following materials: metal, ceramics and resinous materials.

Regarding the claim core build-up indication, the Allcem Core is similar to the reference predicate, Rebilda DC.

K) Technological Characteristics Comparison:

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

Device Manufacturer and Common Name	**Allcem and Allcem Core** **Dentscare**	**Suglue-10** **3M Espe**	**Rebilda DC** **Voco**
510k #	Not assigned yet	K110508	K060893
Classification	Class II	Class II	Class II
Regulation #	21 CFR 872.3275	21 CFR 872.3275	21 CFR 872.3690
Product Code	EMA	EMA	EBF
Classification Name	Dental cement	Dental cement	Tooth shade resin material.
Patient Population	No restriction, it can be applied to general population	No restriction, it can be applied to general population	No restriction, it can be applied to general population
Prescription Use	RX only	RX only	RX only
Environment	Dental prosthetics and authorized laboratories and clinics. Allcem and Allcem Core must be stored in temperatures between 5° to 25°C	Dental prosthetics and authorized laboratories and clinics. predicate must be stored in temperatures between 15° to 25°C	Dental prosthetics and authorized laboratories and clinics. REBILDA DC must be stored in temperatures between 4° to 23°C
Applicable Standards	ISO 4049; ISO 10993-1; ISO 10993-5; ISO 10993-10 ISO 10993-11	ISO 4049; ISO 10993-1; ISO 10993-5; ISO 10993-10 ISO 10993-11	ISO 4049; ISO 10993-1; ISO 10993-10

Composition	Methacrylate monomers, Radiopaque fillers, Initiator components, Stabilizers, Rheological additives, Pigments, Fluorescence dye, activator.	Methacrylate monomers, Radiopaque fillers, Initiator components, Stabilizers, Rheological additives, Pigments, Fluorescence dye, activator.	Methacrylate monomers, Radiopaque fillers, Initiator components, Stabilizers, Rheological additives, Pigments.
Device Sterilization	Not Applicable	Not Applicable	Not Applicable
How the device achieves its intended purpose	Fast light polymerization or long working times in chemical curing Dual-curing materials	Fast light polymerization or long working times in chemical curing Dual-curing materials	Fast light polymerization or long working times in chemical curing Dual-curing materials
Side effects	Systemic side effects are not known to date. In allergic individuals, allergic reactions may occur.	Systemic side effects are not known to date. In allergic individuals, allergic reactions may occur.	Systemic side effects are not known to date. In allergic individuals, allergic reactions may occur
Contra indications and Precautions	The product should not be used in patients allergic to any of the substances contained in the formula. Wear protective gloves.	The product should not be used in patients allergic to any of the substances contained in the formula. Wear protective gloves.	The product should not be used in patients allergic to any of the substances contained in the formula.
Primary Package Container	Syringe or Double Syringe	Double Syringe	Cartridges/Double Syringe (Quick mix syginge)
Shelf life	2 years	18 months	2 years
Claims on product	Dual curing permanent adhesive cementing system	Dual curing permanent adhesive cementing system	Dual curing permanent adhesive cementing system
Use the same materials or substances in contact with the same human tissues or body fluids?	YES	YES	YES
Is the product in compliance to EN ISO 10993 ?	YES	YES	YES
Tissues	Enamel and Dentin	Enamel and Dentin	Enamel and Dentin

Reusable	NO		NO	NO
Duration	Permanent		Permanent	Permanent
Part of body	Oral, tooth		Oral, tooth	Oral, tooth
Is it used for the same clinical condition?	yes		yes	yes
Is it used at the same site in the body?	yes		yes	yes
Is it used in a similar population?	yes		yes	yes
Is it used for the same intended purpose?	yes		yes	yes
Is not foreseen to deliver significantly different performances?	no		no	no
Is it similar conditions of use?	yes		yes	yes
Is it similar specifications and properties	yes		yes	yes
Is it similar principles of operation?	yes		yes	yes
Film thickness	8.8 µm	8.4 µm	14.4 µm	18.6 µm
Working time	> 60 sec	> 60 sec	> 60 sec	> 60 sec
Setting time	07:06 min	07:18 min	06:22 min	06:40 min
Flexular strength	127.7 MPa	112.7 MPa	105.9 MPa	112.0 MPa
Water sorption solubility	Sorption: 29.93 µg/mm^3	Sorption: 28.37 µg/mm^3	Sorption: 25.98 µg/mm^3	Sorption: 26.59 µg/mm^3

	Solubility: 5.62 µg/mm^3	Solubility: 5.57 µg/mm^3	Solubility: 5.54 µg/mm^3	Solubility: 5.00 µg/mm^3
Radio-opacity	2.35 mm	1.17 mm	1.73 mm	0.89 mm
Color **Color stability[1]**	T0 L= 87.60 a= -0.97 b= 16.00 opac.= 48.0 T24 L= 85.42 a= -1.34 b= 19.96 opac.= 51.7	T0 L= 85.80 a= -1.06 b= 16.17 opac.= 51.34 T24 L= 85.34 = -0.89 b= 16.21 opac.= 52,30	Not found	Not found
Shear Bond Strength	ISO 29022 specifies a shear test method used to determine the adhesive bond strength between direct dental restorative materials and tooth structure. The material is a direct restorative material, however, when it is used in contact with the tooth structure, there is the necessity to use adhesive prior, so the contact is indirect.			

[1] The test where performed according to internal procedure (POPRD 0053) for stability test, so the results were obtained from stability tests of the products.

Discussion:

The subject device is similar to the predicate devices in that they are all dual-curing, radio-opaque resin cements to be used for permanently cementing restorations.
The subject device and the predicate devices have substantially equivalent of indications for use, shelf life, physical and mechanical properties. Despite differences in results, all products meet ISO 4049 and the results match the requirements of this International Standard and it does not affect the substantial equivalence.

L) Applicable Standard:

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

EN ISO 4049 Fourth edition 2009-10-01 - Dentistry - Polymer-based restorative materials - Recognition number: 4-181
ISO 10993-1 Fourth edition 2009-10-15 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process - Recognition number: 2-220
ISO 10993-10 Third Edition 2010-08-01 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization - Recognition number: 2-174
ISO 10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity - Recognition number: 2-245
ISO 10993-11 Third edition 2017-09- Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity - Recognition number: 2-255

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device ALLCEM and ALLCEM CORE demonstrate equivalency to the predicates above.

M) Non-clinical Testing:

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

<table>
<tr><th>Test</th><th>Specification</th><th>Results</th></tr>
<tr><td>Flexing Resistance (dual cure)</td><td>According to the EN ISO 4049 standard the specification for flexural strength is ≥50MPa.</td><td>All results are greater than the specified threshold, therefore the material is considered as conformant.
<table><tr><th>Corpo de prova
Specimen</th><th>Resultado
Result</th></tr><tr><td>CP 1</td><td>143,71 MPa</td></tr><tr><td>CP 2</td><td>159,21 MPa</td></tr><tr><td>CP 3</td><td>135,61 MPa</td></tr><tr><td>CP 4</td><td>145,08 MPa</td></tr><tr><td>CP 5</td><td>143,51 MPa</td></tr><tr><td>Média/Average:</td><td>145,4 MPa</td></tr></table></td></tr>
<tr><td>Flexural strength - Chemical Curing</td><td>According to the EN ISO 4049 standard the specification for flexural strength is ≥50MPa.</td><td>All results are greater than the specified threshold, therefore the material is considered to be in conformity
<table><tr><th>Corpo de prova/
Specimen</th><th>Resultado/
Result Mpa</th></tr><tr><td>CP 1</td><td>135,1</td></tr><tr><td>CP 2</td><td>103,6</td></tr><tr><td>CP 3</td><td>139,4</td></tr><tr><td>CP 4</td><td>137,6</td></tr><tr><td>CP 5</td><td>123,0</td></tr><tr><td>Média/Average:</td><td>127,7</td></tr></table></td></tr>
<tr><td>Film Thickness.</td><td>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),</td><td>From the results obtained it is observed that the film thickness is ≤ 40 µm, thus complying with EN ISO 4049.
The test was performed five times and the samples showed the following results:
Reading B - Reading A = film thickness</td></tr>
</table>

	so the result of acceptance must be less than 50 µm	*Sample 1: 10.218mm - 10.187mm = 0.031 mm = 31 µm* *Sample 2: 10.244mm - 10.208mm = 0.036mm = 36 µm* *Sample 3: 10.222mm - 10.184mm = 0.038mm = 38 µm* *Sample 4: 10.223mm - 10.191mm = 0.032mm = 32 µm* *Sample 5: 10.239mm - 10.204mm = 0.035mm = 35 µm*
Working time.	According to the EN ISO 4049 standard, the working time for cementing materials must be at least 60 seconds.	The results demonstrate that the product has a working time greater than 60 seconds. Ideal time for the work of the professional and within the value established by the Standard.
Setting Time	According to the EN ISO 4049 standard, the setting time for the cement material must be a maximum of 10 minutes.	From the results it is observed that the setting time of the material is around 7 minutes, thus meeting the specification in the EN ISO 4049 standard.
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.
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 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.

Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the ALLCEM product in forced conditions of storage.	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 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 24 months of the long-term test (shelf), the shelf life of 2 years in the storage condition of 25°C for the Allcem product can be confirmed.
Adhesive resistance to metal surfaces, pins, ceramics and laboratory resin.	Near or higher than competitors.	Although it is not a standard assay and the adhesion to the dental structure is promoted by adhesives, these tests demonstrate that Allcem has excellent adhesion results.
Shear bond strength (per ISO 29022)	ISO 29022 specifies a shear test method used to determine the adhesive bond strength between direct dental restorative materials and tooth structure. The material is a direct restorative material, however, when it is used in contact with the tooth structure, there is the necessity to use adhesive prior, so the contact is indirect.	

Conclusion: Based on the performance test applied to this ALLCEM and ALLCEM CORE and the predicates comparison, we conclude that the performance and effectiveness for the specified indications for use for these products were reached as well the substantially equivalency with the predicates.