September 4, 2019

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

Re: K190758
Trade/Device Name: Opus Bulk Fill APS, Opus Bulk Fill Flow APS
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 3, 2019
Received: June 7, 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)*

K190758

Device Name
Opus Bulk Fill APS and Opus Bulk Fill Flow APS

Indications for Use *(Describe)*

Opus Bulk Fill APS
- Direct restorations in posterior teeth (permanent and deciduous) in increments of up to 5mm, including the occlusal surface;
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Reconstructive build-up;-
- Base and lining of direct restorations;
- Repair of small defects of the enamel;
- Repair of temporary acrylic and resin materials

Opus Bulk Fill Flow APS
- Base/lining underneath 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 enamel defects
- Bonding of tooth fragments.
- Repair in composite resin
- Non-carious cervical lesions.
- Planning of preparation walls.
- 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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DENTSCARE LTDA
AV. EDGAR NELSON MEISTER, 474, JOINVILLE,
SANTA CATARINA 89219-501 BRAZIL
Ph: 55 - 47 – 3441-6131

Section 5
510(k) SUMMARY

K190758

June 13, 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: June 13, 2019

F) Classification Name: Tooth Shade Resin Material

Common / Usual Name: Tooth shade resin material.

Proprietary Name: Opus Bulk Fill APS and Opus Bulk Fill Flow APS

Product Code: EBF

Class: Class II

Regulation: 21 CFR 872.3690

G) Device Description

Opus Bulk Fill APS

Opus Bulk Fill APS is a light-curing composite recommended for restorations performed in large increments. The technical characteristics of the product allow the professional to use increments of up to 5mm in the cavities, including the occlusal

surface (it does not require an additional capping layer). The composite has approximately 79% of load filler (in mass).

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.

Opus Bulk Fill Flow APS

Opus Bulk Fill Flow is a bulk-fill flowable light-curing composite (fluid) recommended to be used as base and lining of restorations on posterior teeth. That feature associated to its cure depth – due to the composite's translucency – allows Opus Bulk Fill Flow to be applied in increments of up to 4mm, reducing the time for restoring large cavities.

H) Substantial Equivalence:

The Opus Bulk Fill APS and Opus Bulk Fill Flow APS is equivalent with the following products:

Equivalence	510(k) Number	Model	Company
Predicate	K111958	TETRIC EVOCERAM BULK FILL	IVOCLAR VIVADENT AG
Reference	K150393	TETRIC EVOFLOW BULK FILL	IVOCLAR VIVADENT AG

I) Indications for Use:

Indications for Use Comparison		
Opus Bulk Fill APS and Opus Bulk Fill Flow APS	**TETRIC EVOFLOW BULK FILL TETRIC EVOCERAM BULK FILL**	**Discussion**
Opus Bulk Fill APS - Direct restorations in posterior teeth (permanent and deciduous) in increments of up to 5mm, including the occlusal surface; - Class V restorations (cervical caries, root erosion, wedge-shaped defects) - Reconstructive build-up;- - Base and lining of direct restorations; - Repair of small defects of the enamel; - Repair of temporary acrylic and resin materials **Opus Bulk Fill Flow APS** - Base/lining underneath 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 enamel defects - Bonding of tooth fragments. - Repair in composite resin - Non-carious cervical lesions. - Planning of preparation walls. - Core build-up	**Tetric Evoceram Bulk Fill (Predicate)** - Restoration of Deciduous teeth - Restorations in the posterior region (Classes I and II) - Class V restorations (cervical caries, root erosion, wedge-shaped defects) - Extended fissure sealing in molars and premolars **Tetric Evoflow Bulk Fill (Reference)** – As initial layer / first increment in Class I and II composite restorations in permanent teeth – Restorations in deciduous teeth	**Opus Bulk Fill APS x Tetric Evoceram Bulk Fill** Reconstructive build-up, base and lining of direct restorations, repair of small defects of the enamel and repair of temporary acrylic and resin materials are examples of direct restauration. As a conclusion, the subject and the predicate have the same indication of use. **Opus Bulk Fill Flow APS x Tetric Evoflow Bulk Fill** - Base/lining: are the restorations made under other restorative material, such as initial layer. This main indication has as examples: Tunnel-type preparation, Planning of preparation walls and Core build-up. - Small, non occlusal stress-bearing class I restorations according to minimally invasive filling therapy: restorations made in regions that do not receive direct masticatory load, according to a minimally invasive therapy. The following indications are related to this definition: Pit and fissure sealant, Repair of enamel defects, Bonding of tooth fragments, Repair in composite resin and Non-carious cervical lesions. Since the product Tetric Evoflow Bulk Fill is indicated for restorations in deciduous teeth, not limiting your use as initial layer, it's imply the material can be applied in occlusal surface in this situation. Taking into account that the deciduous dentition receives a lower masticatory load, the situation of these indications mentioned above in permanent teeth fits in the same situation. Restorations are clinical known for indication to permanent and deciduous teeth.

J) Technological Characteristics Comparison:

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

Device Manufacturer and Common Name	**Opus Bulk Fill APS and Opus Bulk Fill Flow APS Dentscare**	**TETRIC EVOCERAM BULK FILL IVOCLAR VIVADENT AG (Predicate)**	**TETRIC EVOFLOW BULK FILL IVOCLAR VIVADENT AG (Reference)**
510k #	Not assigned yet	K111958	K150393
Classification	Class II	Class II	Class II
Regulation #	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3690
Product Code	EBF	EBF	EBF
Classification Name	Tooth Shade Resin Material	Tooth Shade Resin Material	Tooth Shade Resin Material
Patient Population	All the groups	All the groups	All the groups
Prescription Use	RX only	RX only	RX only
Environment	Dental prosthetics and authorized laboratories and clinics. Opus Bulk Fill APS and Opus Bulk Fill Flow APS must be stored in temperatures between 5° to 27°C.	Dental prosthetics and authorized laboratories and clinics. TETRIC must be stored in temperatures between 2° to 28°C	Dental prosthetics and authorized laboratories and clinics. TETRIC must be stored in temperatures between 2° to 28°C
Applicable Standards	ISO 4049 ; ISO 10993-1	ISO 4049; ISO 10993-1	ISO 4049; ISO 10993-1
Device Sterilization	Not Applicable	Not Applicable	Not Applicable
Primary Package Container :	Syringe and Capsule	Syringe and Capsule	Syringe and Capsule

Shelf life	2 years	Not declared	Not declared
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, teeth	Oral, teeth	Oral, teeth
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

	Opus Bulk Fill APS	**Opus Bulk Fill Flow APS**	**Tetric Evoceram Bulk Fill**
Layer thickness/Curing Depth	4.61 mm	4.39 mm	3.65 mm
Sensitivity to ambient light	Homogeneous	Homogeneous	Homogeneous
Flexural Strength	129.80 MPa	84.47 MPa	101.2 MPa
Water Sorption	26.85 µg/mm^3	29.06 µg/mm^3	29.00 µg/mm^3
Solubility	5.61 µg/mm^3	5.46 µg/mm^3	5.21 µg/mm^3
Radiopacity	2.09 mm	2.36 mm	1.58 mm
Color stability	Stable	Stable	Stable

Discussion:

The subject device is similar to the predicate devices in that they are all dual-curing, radio-opaque and self-adhesive 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 product physical properties, these do not impact the safety and performance of the product, since all products meet the International Standard ISO 4049 requirements and it does not affect the substantial equivalence.

K) Applicable Standards:

In order to reach substantially equivalent to the predicate device the device Opus Bulk Fill APS and Opus Bulk Fill Flow 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 Opus Bulk Fill APS and Opus Bulk Fill Flow APS demonstrate equivalency to the predicates above.

L) Risk Management

In order to identified and mitigate the risks to health associated with the use of dental composite resin we have developed the risk analysis management file which includes the risk analysis method and results.

M) 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.

OPUS BULK FILL APS

In order to study the performance of the product, pre-clinical tests were performed according to EN ISO 4049, table below with the results found.

Test	Specification	Results
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.
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.
Colour tone stability after radiation and water absorption - ISO 4049 and ISO 7491	The acceptance must be performed provided that there is no more than a small change in colour, it must be proven as follows: a)comparisons should be made by visual inspection and analysed by three observers with normal vision, who do not identify any differences in 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 (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.
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	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

	value for the δs thickness of the specimen and determine the corresponding value of aluminium, δa.	
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.
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.
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.
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.
Fluoride release	Evaluation of fluoride release rate in solution after 7 days in the oven at 37o C	The results of the fluoride release assay demonstrate no release of fluoride ions.
Intensity and wavelength for photocuring	Study designed to evaluate the curing depth using photopolymerizes with different wavelengths and power density	The test results demonstrate the ability polymerization resin with differencing light devices.
Filler particle size distribution (microns)	Study designed to verify the grainsize analysis and optical characteristics.	The test results demonstrate the microns within the specifications.

OPUS BULK FILL FLOW APS

In order to study the performance of the product, pre-clinical tests were performed according to EN ISO 4049, table below with the results found.

Test	Specification	Results
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.

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.
Colour tone stability after radiation and water absorption - ISO 4049 and ISO 7491	The acceptance must be performed provided that there is no more than a small change in colour, it must be proven as follows: a)comparisons should be made by visual inspection and analysed by three observers with normal vision, who do not identify any differences in 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 (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.
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
Flexing Resistance - ISO 4049	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 as conformant.
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.
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 149 days test period, the shelf-life of 2 years in the storage condition of 27 °C for the product can be confirmed.
Evaluation Report Of Long-	Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results	We don't have any conclusive data about shelf life yet. At the moment we are using the estimated shelf life in 2

Term Stability (Shelf)	are used to confirm the expiration date and storage conditions.	years in the storage condition of 27 ° C, based on no accelerated stability test.
Filler particle size distribution (microns)	Study designed to verify the grainsize analysis and optical characteristics.	The test results demonstrate the microns within the specifications.

Conclusion: Based on the performance test applied to this Opus Bulk Fill APS and Opus Bulk Fill Flow APS and the predicate comparison, we conclude that the subject device is substantially equivalent to the predicate.