June 21, 2019

Coltene/Whaledent AG
Wolfgang Dorner
Regulatory Affairs Specialist
Feldwiesenstrasse 20
Altstatten, 9450 SWITZERLAND

Re: K190597
Trade/Device Name: BRILLIANT EverGlow Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: April 1, 2019
Received: April 4, 2019

Dear Wolfgang Dorner:

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, PhD
Acting Assistant 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)*

K190597

Device Name
BRILLIANT EverGlow Flow

Indications for Use *(Describe)*

BRILLIANT EverGlow Flow Universal and Translucent shades are suitable for:
• Direct class V fillings (cervical caries, root erosion, wedge-shaped defects)
• Fillings in the anterior tooth region (Class III and IV)
• Small fillings of all cavity classes (not occlusion-bearing)
• Blocking out of undercuts
• Adhesive luting of indirect composite and ceramic restorations in as far as accuracy of fit and light permeability are given
• Repairs of direct and indirect composite restorations
• Preventive resin restorations
• Cavity lining

BRILLIANT EverGlow Flow opaque shade is also suitable for:
• Aesthetic corrections (e.g. deviations in chroma)
• Masking of dark areas

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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K190597

Section 5 - 510(k) Summary

1. Submitter

Company Name:	Coltène/Whaledent AG
Street and Nr.:	Feldwiesenstrasse 20
City:	Altstätten
Post Code:	9450
State/Canton:	Sankt Gallen
Country:	Switzerland
Main Contact:	Wolfgang Dörner
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Phone:	+ 41 71 757 5422
Email:	wolfgang.doerner@coltene.com

2. Date Prepared

1. March 2019

3. Device Identification

Trade Name:	BRILLIANT EverGlow Flow®
Common Name:	Flowable radiopaque submicron hybrid composite
Classification Name:	Tooth shade resin material
Regulation Number:	872.3690
Product Code:	EBF
Class:	II
Classification Panel:	Dental

4. Legally Marketed Predicate Device(s)

The predicate device for BRILLIANT EverGlow Flow is BRILLIANT EverGlow from Coltène/Whaledent. BRILLIANT EverGlow was cleared under the 510(k) number K152927 on 28. April 2019 (Exhibit 5-1).

5. Indication for Use

BRILLIANT EverGlow Flow Universal and Translucent shades are suitable for:

- Direct class V fillings (cervical caries, root erosion, wedge-shaped defects)
- Fillings in the anterior tooth region (Class III and IV)
- Small fillings of all cavity classes (not occlusion-bearing)
- Blocking out of undercuts
- Adhesive luting of indirect composite and ceramic restorations in as far as accuracy of fit and light permeability are given
- Repairs of direct and indirect composite restorations
- Preventive resin restorations
- Cavity lining

BRILLIANT EverGlow Flow opaque shade is also suitable for:

- Aesthetic corrections (e.g. deviations in chroma)
- Masking of dark areas

6. Device Overview

BRILLIANT EverGlow Flow is a flowable radiopaque submicron hybrid composite and available in several shades that allows for high aesthetic restorations with a clear spectrum of shades. It is applied in the increment technique and available in 7 universal, 2 translucent and 3 opaque shades.

BRILLIANT EverGlow Flow is chemically characterized by its composition, which can be categorized in three groups based on their chemical and functional similarity: resin components (matrix monomers based on methacrylates), fillers, and additives. The largest part of BRILLIANT EverGlow Flow's composition is represented by fillers (>58% w/w), followed by resin components (<40% w/w), and

additives (<2% w/w). BRILLIANT EverGlow Flow is, after curing, a crosslinked methacrylate-based composite material with a three-dimensional polymer network, containing embedded filler particles and incorporated additives. A detailed description of the chemical composition can be found in **Table 3.**

BRILLIANT EverGlow Flow has long term contact (>30 days) with tissue/bone/dentin.

BRILLIANT EverGlow Flow is the supplemental flowable, radiopaque submicron hybrid material version of the universal composite BRILLIANT EverGlow. BRILLIANT EverGlow Flow is, due to its lower viscosity, considered an enhancement of BRILLIANT EverGlow for applications with non-easily accessible areas in the oral cavity (e.g. blocking out of undercuts) and/or extended fissure-sealing. BRILLIANT EverGlow Flow combines a low viscous consistency with high stability and thixotropy, allowing a controlled and comfortable application. BRILLIANT EverGlow Flow is available in different shades and gradations of translucency. BRILLIANT EverGlow Flow is delivered with two application needle sizes (standard size [Ø 0.8mm] and fine size [Ø 0.4mm]). The fine size needle is to improve the accessory range and to allow an application with higher precision.

Figure 1: BRILLIANT EverGlow Flow® is available in syringes (à 2 g) with two application needle sizes (Ø 0.8mm and Ø 0.4mm).

7. Substantial Equivalence Discussion

A comparison of the new device BRILLIANT EverGlow Flow to the predicate device BRILLIANT EverGlow device with respect to its physical state, structure, materials, mechanical properties, indications for use, packaging, biocompatibility and performance testing, is shown in **Table 1** and **Table 2**.

Table 1: Comparison of overall device characteristics

Attributes	New Device	Predicate Device
Device Name	BRILLIANT EverGlow Flow®	BRILLIANT EverGlow®.
Manufacturer	Coltène/Whaledent AG, Switzerland	Coltène/Whaledent AG, Switzerland
510(k) #	-	K152927
Product Code	EBF	EBF
Regulation number (21 CFR):	872.3690	872.3690
Class	II	II
Review Panel	Dental	Dental
Physical State	Viscous paste	Viscous paste
Structure	Polymer resin composite	Polymer resin composite
Sizes	Prefilled syringes à 2 g	Prefilled syringes à 3 g and tips à 0.2 g
Main composition of material	Methacrylates Dental glass Amorphous silica Zinc oxide	Methacrylates Dental glass Amorphous silica Zinc oxide
Technical Data	Range of dimensions of inorganic filler particles: 0.02-1.5 µm Inorganic filler content by volume: 37 % Inorganic filler content by weight: 60 %	Range of dimensions of inorganic filler particles: 0.02–1.5 µm Inorganic filler content by volume: 56 % Inorganic filler content by weight: 74 %
Indications for Use	BRILLIANT EverGlow Flow **universal and translucent**	BRILLIANT EverGlow **universal** shades Bleach (BL),

Attributes	New Device	Predicate Device
	shades are suitable for: - Direct class V fillings (cervical caries, root erosion, wedge-shaped defects) - Fillings in the anterior tooth region (Class III and IV) - Small fillings of all cavity classes (not occlusion-bearing) - Blocking out of undercuts - Adhesive luting of indirect composite and ceramic restorations in as far as accuracy of fit and light permeability are given - Repairs of direct and indirect composite restorations - Preventive resin restorations - Cavity lining BRILLIANT EverGlow Flow **opaque shade** is also suitable for: - Aesthetic corrections (e.g. deviations in chroma) - Masking of dark areas	A1/B1, A2/B2, A3/D3, A3,5/B3, C2/C3 and A4/C4 are indicated for: - Direct filling of class I, II, III, IV and V cavities - Luting and repairing of ceramic and composite restorations (e.g. COMPONEERR) BRILLIANT EverGlow translucent shades **Translucent** (Trans) and **Bleach Translucent** (BL Trans) are indicated for: - Shape and color corrections to enhance the individual esthetics - Reconstruction of incisal edges - Luting and repairing of ceramic and composite restorations (e.g. COMPONEERR) BRILLIANT EverGlow **opaque shades** Opaque Bleach (OBL), Opaque A1 (OA1) and Opaque A3 (OA3) are indicated for: - Aesthetic corrections (e.g. chroma deviations) - Masking of dark areas - Forming of a dentin core
Packaging	Prefilled syringes	Prefilled syringes, tips
Usage	Single Patient, multiple use	Single Patient, multiple use

Attributes	New Device	Predicate Device
	Application by increment technique	Application by increment technique
Sterility	non-sterile	non-sterile
Biocompatibility	Conforms with ISO 10993-1:2018	Conforms with ISO 10993-1:2018
Performance	Conforms with ISO 4049:2009	Conforms with ISO 4049:2009

Table 2: Comparison of main physical and mechanical properties of BRILLIANT EverGlow Flow® with BRILLIANT EverGlow

Criteria	Subject Device: BRILLIANT EverGlow Flow	Predicate Device BRILLIANT EverGlow Flow	Unit
Flexural strength	96	117	MPa
Compressive strength	415	390	MPa
Exposure time and Intensity for curing (for photo-initiated resins)	20s with 800 10s with 1600	20s with 800 10s with 1600	mW/cm^2
Inorganic filler content	37	74	Vol-%
Radio-opacity	2.2	2.0	mm of Al
Water sorption	23	15	$\mu g/mm^3$
Water Solubility	2.0	0.7	$\mu g/mm^3$

Table 3: Chemical Composition of BRILLIANT EverGlow Flow and the predicate device BRILLIANT EverGlow

Subject Device: **BRILLIANT EverGlow Flow**	**Predicate Device:** **BRILLIANT EverGlow**
Methacrylates Dental glass Amorphous silica Zinc oxide Colorants and Additives	Methacrylates Dental glass Amorphous silica Zinc oxide Colorants and Additives
Range of dimensions of inorganic filler particles: 0.02-1.5 µm Inorganic filler content by volume: 37 % Inorganic filler content by weight: 60 %	Range of dimensions of inorganic filler particles: 0.02–1.5 µm Inorganic filler content by volume: 56 % Inorganic filler content by weight: 74 %
Complies with ISO 4049	Complies with ISO 4049

8. Non-Clinical Performance Data

As part of demonstrating substantial equivalence of BRILLIANT EverGlow Flow to the predicate device, Coltène/Whaledent extensive testing of the finished device was done in accordance with the applicable parts of the following voluntary standards, as well as to the company's own internal test protocol.

1. ISO 10993-1:2018 - *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
2. EN ISO 14971:2012 - *Medical devices – Application of risk management to medical devices.*
3. FDA General Guidance: 2016 - *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
4. ISO 7405:2018 – *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*

The testing evaluated flexural strength, flexural modulus, compressive strength, and biocompatibility of the subject device, as well as other related physical properties. The subject device passed all required testing.

9. Statement of Substantial Equivalence

BRILLIANT EverGlow Flow has the same intended use, indications for use and similar physical attributes as BRILLIANT EverGlow. Any minor differences in the materials used to make the subject device when compared to the predicate device have been successfully evaluated by Coltène/Whaledent through extensive performance and biocompatibility testing on the device, such that the information submitted to the FDA demonstrates that the subject device is as safe and effective as the predicate device and does not raise any new questions of safety and effectiveness. BRILLIANT EverGlow Flow, as designed and manufactured by Coltène/Whaledent, has been determined to be substantially equivalent to BRILLIANT EverGlow.