October 29, 2019

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

Re: K191385
Trade/Device Name: BRILLIANT COMPONEER
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 29, 2019
Received: July 31, 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,

for Srinivas Nandkumar, Ph.D.
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)*
K191385

Device Name
BRILLIANT COMPONEER

Indications for Use *(Describe)*
Indication
Clinical indications
— Restoration of caries defects
— Reconstruction of lost tooth substance due to attrition, abrasion, erosion
— Restoration of tooth fractures
— Correction of anatomical malformation

Cosmetic indications
— Optimisation of old composite restorations
— Extending incisors
— Correction of malpositioned teeth
— Cosmetic corrections for tooth discolouration or incorrect shading
— Closure of diastema

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K191385

Section 5 - 510(k) Summary

5.1 Submitter:

Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten
Sankt Gallen
Switzerland

5.2 Submitter Contact:

Contact:	Wolfgang Dörner
Title:	Regulatory Affairs Specialist
Phone:	+41 71 757 5422
Email:	wolfgang.doerner@coltene.com

5.3 Date Prepared

25th October 2019

5.4 Device Identification

Type of 510(k) Submission:	Traditional 510(k)
510(k) Number:	K191385
Trade Name:	BRILLIANT COMPONEER
Common Name:	Tooth shade resin material
Regulation Number:	872.3690
Product Code:	EBF
Class:	II
Classification Panel:	Dental

5.5 Primary Predicate Device

The primary predicate device is COMPONEER and is manufactured by Coltène/Whaledent AG in Switzerland. The primary predicate device was cleared in 2011 under the 510(k) number K112168.

5.6 Indication for Use

BRILLIANT COMPONEER is indicated for:
Clinical indications

- Restoration of caries defects
- Reconstruction of lost tooth substance due to attrition, abrasion, erosion
- Restoration of tooth fractures
- Correction of anatomical malformation

Cosmetic indications

- Optimization of old composite restorations
- Extending incisors
- Correction of malpositioned teeth
- Cosmetic corrections for tooth discoloration or incorrect shading
- Closure of diastema

5.7 Device Overview

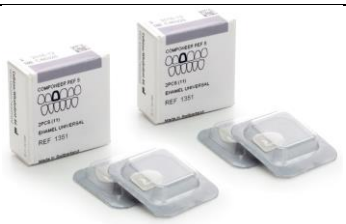
The subject device BRILLIANT COMPONEER is a polymerized, prefabricated, highly filled, submicron hybrid composite enamel shell(s) for direct veneering. It simplifies the direct restoration of front teeth and premolars without having to model the basic shape of the top enamel layer. The thin, anatomical composite shells are available in different shades and shapes allowing a natural, high aesthetic restoration (**Figure 1**).

Figure 1: BRILLIANT COMPONEER package overview and veneers (on the right).

5.8 Substantial Equivalence

A comparison of the subject device BRILLIANT COMPONEER to the primary predicate device COMPONEER (K112168) is provided in **Table 1**.

Table 1: Comparison of BRILLIANT COMPONEER and COMPONEER

Attributes	Subject Device BRILLIANT COMPONEER	Primary Predicate Device COMPONEER
Device Name	**BRILLIANT COMPONEER**	**COMPONEER**
Manufacturer	Coltène/Whaledent AG, Switzerland	Coltène/Whaledent AG, Switzerland
510(k) #	K191385	K112168
Product Code	EBF	EBF
Classification Name:	Tooth shade resin material	Tooth shade resin material
Regulation	21 CFR 872.3690	21 CFR 872.3690
Class	II	II
Review Panel	Dental	Dental
Device Image		
Physical State:	Polymerized prefabricated hybrid composite enamel shells.	Polymerized prefabricated hybrid composite enamel shells.
Structure:	Polymer resin composite	Polymer resin composite
Resin Matrix Monomers:	Methacrylates	Methacrylates
Inorganic Filler:	Barium glass and silica	Barium glass and silica
Sizes:	Maxillary veneers available in size S, M, L and XL. Mandibular veneers available in in sizes S or M	Maxillary veneers available in size S, M, L and XL. Mandibular veneers available in in sizes S or M
Indications for Use	Clinical indications: - Restoration of caries defects - Reconstruction of lost tooth substance due to attrition, abrasion, erosion - Restoration of tooth fractures - Correction of anatomical malformation Cosmetic indications - Optimisation of old composite	- Restoration therapy for caries - Optimization of old restorations - Extending incisors - Malpositioned teeth - Tooth fractures - Tooth discoloration, incorrect shading - Anatomical malformation - Diastema - Attrition, abrasion, erosion

Attributes	Subject Device BRILLIANT COMPONEER	Primary Predicate Device COMPONEER
	restorations - Extending incisors - Correction of malpositioned teeth - Cosmetic corrections for tooth discolouration or incorrect shading - Closure of diastema	- Cosmetic correction
Primary Packaging	Blisters with single veneers	Blisters with single veneers
Usage	Single patient, single use	Single patient, single use
Sterility	Non-sterile	Non-sterile
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1
Performance	Conforms with ISO 4049	Conforms with ISO 4049
Compressive Strength:	285 MPa	392 MPa
Flexural Strength:	125.4 MPa	127 MPa
Elastic Modulus:	9.8 GPa	9.0 GPa
Radiopacity:	3.24 mm of Al	2 mm of Al
Water sorption:	18.2 µg / mm^3	16 µg / mm^3
Solubility:	0.3 µg / mm^3	0.9 µg / mm^3

5.9 Non-Clinical Performance Testing

As part of demonstrating substantial equivalence of the subject device BRILLIANT COMPONEER to the primary predicate device COMPONEER, Coltène/Whaledent AG performed extensive testing of the finished device in accordance with the applicable parts of the following standards, as well as according to the company's additional internal test protocols.

1. EN 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
5. ISO 4049:2009 Dentistry-Polymer-based filling, restorative and luting materials

The test results showed that BRILLIANT COMPONEER is biocompatible and performs as intended based on the biocompatibility and bench tests according to the applicable standards. In Table 2 a list of the conducted tests is provided.

Table 2: List of tests completed for BRILLIANT COMPONEER

Biocompatibility
Chemical Characterization of Extractable Organic Compounds
In vitro Cytotoxicity Assay
Bacterial Reverse Mutation Assay
Acute Systemic Toxicity
Subchronic Systemic Toxicity
Biological Evaluation Report
Irritation Assessment
Acute Systemic Toxicity Assessment
Sensitization Assessment
Bench Testing
Water sorption
Solubility
Flexural strength
Compressive Strength
Elastic Modulus
Filler Particle Size Distribution
Surface Hardness / Vickers hardness
Radiopacity
Water sorption
Solubility

Animal and clinical performance testing was not included.

5.10 Statement of Substantial Equivalence

BRILLIANT COMPONEER has a similar intended use, indications for use, physical and chemical attributes, as the predicate device COMPONEER. 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 AG through extensive performance and biocompatibility testing on the device. In conclusion, the subject device BRILLIANT COMPONEER has been determined to be substantially equivalent to the predicate device COMPONEER.