Coltene/Whaledent AG
% Stuart Goldman
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

August 15, 2018

Re: K181500
Trade/Device Name: BRILLIANT Crios
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 1, 2018
Received: June 7, 2018

Dear Stuart Goldman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181500

Device Name
BRILLIANT Crios

Indications for Use *(Describe)*
BRILLIANT Crios is indicated for:

- Crowns, inlays, onlays and veneers
- Implant-supported crowns

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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510(k) Summary

K181500

BRILLIANT Crios

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Stuart R. Goldman
Title: Senior Consultant RA/QA
Phone: (512) 327-9997

3. Date Prepared

June 1, 2018

4. Device Identification

Trade Name:	BRILLIANT Crios
Common Name:	Restorative resin material
Classification Name:	Tooth shade resin material
Regulation Number:	872.3690
Product Code:	EBF
Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

- CERASMART™ (K133824); Manufacturer: GC America, Inc.
- Coltène/Whaledent AG is also using their own device, SYNERGY® (K974465) as a Reference Device.

6. Indication for Use

BRILLIANT Crios is indicated for:

- Crowns, inlays, onlays and veneers

- Implant-supported crowns.

7. Device Overview

BRILLIANT Crios is a radiopaque composite material composed of crosslinked methacrylate based polymerized monomers and dental glass fillers. The subject device is made available in block forms of different sizes, shades and translucencies for the fabrication of permanent tooth restorations such as inlays, onlays, crowns and veneers using CAD/CAM milling equipment.

8. Substantial Equivalence Discussion

Table 5-1 compares BRILLIANT Crios blocks to the predicate device with respect to its physical state, structure, materials, mechanical properties, indications for use, packaging, biocompatibility and performance testing, and provides detailed information regarding the basis for the determination of substantial equivalence. The reference device is also included in this table for comparative purposes.

Table 5-1 – Comparison of Device Characteristics

Attributes	Reference Device	Predicate Device	Subject Device	Similarities / Differences
Device Name	SYNERGY®	CERASMART™	BRILLIANT Crios	-
Manufacturer	Coltène/Whaledent	GC America	Coltène/Whaledent	-
510(k) #	K974465	K133824	Pending	-
Product Code	EBF	EBF	EBF	Same
Regulation	§872.3690	§872.3690	§872.3690	Same
Class	II	II	II	Same
Review Panel	Dental	Dental	Dental	Same
Device Image				-
Indications for Use	SYNERGY is indicated for: • direct filling of class I, II, III, IV and V cavities, • reconstruction	The product is indicated for inlays, onlays, veneers and full crown restorations, including crowns on	BRILLIANT Crios is indicated for: - Crowns, inlays, onlays and veneers - Implant-supported crowns	The subject and predicate device have the same intended use and are used for permanent tooth restorations.

Attributes	Reference Device	Predicate Device	Subject Device	Similarities / Differences
	of natural enamel and dentine, • reconstruction of fractured anteriors, • sealing of extended fissures in molars and premolars, • stabilization of mobile anteriors, • repair of veneer facings, • fixation of splints, • bonded bridges, • esthetic	implants		
Physical State	Viscous paste	Cured blocks	Cured blocks	The subject and predicate device are supplied as cured blocks and CAD/CAM milled into the final dental restoration.
Structure	Polymer resin composite	Polymer resin / ceramic hybrid composite	Polymer resin composite	The subject device has an all polymer resin matrix while the predicate device has a polymer resin / ceramic hybrid matrix.
Resin Matrix Monomers	Bis-GMA, Bis-EMA, TEGDMA	Bis-MEPP, UDMA, DMA	Bis-GMA, Bis-EMA, TEGDMA, UDMA	The subject and predicate device both contain UDMA in their resin matrix.
Filler	Silica, barium glass	Silica, barium glass	Silica, barium glass	Same
Sizes	na	12, 14 and 14L	12, 14	The subject device size ranges fall within

Attributes	Reference Device	Predicate Device	Subject Device	Similarities / Differences
				those of the predicate device.
Flexural Strength	125 (MPa)	160 (MPa)	198 (MPa)	Similar
Flexural Modulus of	6.8 (GPa)	8.3 (GPa)	10.3 (GPa)	Similar
Compressive Strength	390 (MPa)	429 (MPa)	426 (MPa)	Similar
Packaging	Plunger syringe type (2.3 g)	Mandrel mounted; five to a box	Mandrel mounted; five to a box	The subject and predicate device are packaged the same way based on their physical state.
Usage	Single Patient, multiple use	Single Patient, multiple use	Single Patient, multiple use	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Same
Performance	Conforms with ISO 4049	Conforms with ISO 4049	Conforms with ISO 4049	Same

9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence of BRILLIANT Crios blocks to the predicate device, Coltène/Whaledent submitted final finished devices for extensive testing in accordance with the applicable parts of the following voluntary standards, as well as to the company's own internal test protocols:

- ISO 4049, *Dentistry – Polymer-based Restorative Materials*
- ISO 7405, *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- ISO 10993-1, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process*

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.

10. Statement of Substantial Equivalence

BRILLIANT Crios blocks have the same intended use, indications for use, physical attributes, and are fabricated into permanent tooth restorations using the same CAD/CAM manufacturing methods as CERASMART™ blocks. 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 their 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 Crios blocks, as designed and manufactured by Coltène/Whaledent, have been determined to be substantially equivalent to CERASMART™ blocks.