February 3, 2021

Tokuyama Dental Corporation
% Keith Baritt
Correspondent
Fish & Richardson P.C.
1000 Maine Avenue, S.W.
Suite 1000
Washington, District of Columbia 20024

Re: K203598
Trade/Device Name: Omnichroma Flow Bulk
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: December 8, 2020
Received: December 9, 2020

Dear Keith Baritt:

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 Michael Adjodha
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)*
K203598

Device Name

OMNICHROMA FLOW BULK

Indications for Use *(Describe)*

For use as a tooth shade resin material in dental procedures such as:

- Direct anterior and posterior restorations
- Cavity base or liner
- Blocking out cavity undercuts before fabricating indirect restorations
- Repair of porcelain/composite

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
Tokuyama Dental Corporation
OMNICHROMA FLOW BULK
tooth shade resin material

K203598

Submitter

(i) 510(k) Submitter

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(ii) 510(k) Submitter Contact

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(iii) Preparation Date

February 2, 2021

Device

Trade or Proprietary Name:	OMNICHROMA FLOW BULK
Common Name:	tooth shade resin material
Classification Name:	material, tooth shade, resin
Class:	2
Product Code:	EBF

Predicate Device

Primary Predicates: Tokuyama Dental Corp.'s ESTELITE BULK FILL Flow (K#161353) and OMNICHROMA FLOW (K#193537)

Reference Devices for Performance:
Tokuyama Dental Corp.'s ESTELITE UNIVERSAL FLOW High (K#180613)

Additional Reference Devices for Biocompatibility:
Tokuyama Dental Corp.'s OMNICHROMA (K#173275) and ESTELITE FLOW QUICK High Flow (K#051808)

Device Description

The OMNICHROMA FLOW BULK is a low viscosity, light-cured, radiopaque composite tooth shade resin material for use in anterior and posterior restorations and is indicated for all carious classes. The OMNICHROMA FLOW BULK device is a single shade material. Direct placement of the OMNICHROMA FLOW BULK device into a prepared cavity allows for easily handling. The OMNICHROMA FLOW BULK device is a flowable material which can be placed in 3.5mm increments.

The OMNICHROMA FLOW BULK device contains 1,6-bis(methacryl-ethyloxycarbonylamino)trimethyl hexane (UDMA), triethylene glycol dimethacrylate (TEGDMA), mequinol, dibutyl hydroxyl toluene, and UV absorber.

OMNICHROMA FLOW BULK is designed to be cured by either a halogen or LED curing-light with a wavelength of 400-500 nm.

The device is intended for use by licensed healthcare professionals only. The device does not come sterilized and is not intended to be sterilized prior to use.

Indications for Use

For use as a tooth shade resin material in dental procedures such as:

- Direct anterior and posterior restorations
- Cavity base or liner
- Blocking out cavity undercuts before fabricating indirect restorations
- Repair of porcelain/composite

Comparison of Technological Characteristics

The OMNICHROMA FLOW BULK device has the same basic technological characteristics in terms of design, material, and chemical composition as the predicate device identified above, as each device is a tooth shade resin material that is cured by photo polymerization. The OMNICHROMA FLOW BULK device does not have its own energy source.

For purposes of performance characteristics for obtaining FDA marketing authorization, the OMNICHROMA FLOW BULK device is substantially equivalent to Tokuyama's own predicate devices, the ESTELITE BULK FILL Flow device (K#161353) and the OMNICHROMA FLOW (K#193537), as shown below:

		Subject device	Predicate #1	Predicate #2	Difference
Device name		OMNICHROMA FLOW BULK	ESTELITE BULK FILL Flow	OMNICHROMA FLOW	-
Manufacturer		Tokuyama Dental	Tokuyama Dental	Tokuyama Dental	-
510(k) No.		K203598	K161353	K193537	-
Health Canada licence No.		(Pending)	98095	104170	
Classification name		Material, Tooth Shade, Resin	Material, Tooth Shade, Resin	Material, Tooth Shade, Resin	-
Indications for Use		For use as a tooth shade resin material in dental procedures such as: - Direct anterior and posterior restorations - Cavity base or liner - Blocking out cavity undercuts before fabricating indirect restorations - Repair of porcelain/composite	For use as a tooth shade resin material in dental procedures such as: - Direct anterior and posterior restorations - Cavity lining - Blocking out cavity undercuts before fabricating indirect restorations - Repair of porcelain/composite	- Direct anterior and posterior restorations - Cavity base or liner - Repair of porcelain/composite	Similar The indications for Use of subject device is within that of the predicate and reference devices.
Component	Container	Syringe	Syringe or Pre-loaded tip	Syringe	Similar The container type of subject device is within that of the predicate and reference devices.
	Shade	1 shade	4 shades	1 shade	Similar The number of shade of subject device is within that of the predicate and reference devices.
Principle of operation		Tooth shade resin material that is cured by photo polymerization. (Light-cure)	Tooth shade resin material that is cured by photo polymerization. (Light-cure)	Tooth shade resin material that is cured by photo polymerization. (Light-cure)	Identical

Material	Filler	- Silica-zirconia filler -Composite filler	- Silica-zirconia filler - Composite filler	- Silica-zirconia filler - Composite filler	Similar The subject device consists mainly of fillers and methacrylates as with the predicate and reference devices. The biocompatibility of the device has been thoroughly evaluated and performance tested.
	Resin matrix monomer	-1,6-bis(methacryl-ethyloxy carbonylamino)trimethyl hexane (UDMA) -Triethylene glycol dimethacrylate (TEGDMA)	- Bisphenol A di(2-hydroxypropoxy) dimethacrylate (Bis-GMA) - Bisphenol A polyethoxy methacrylate (Bis-MPEPP) - Triethylene glycol dimethacrylate (TEGDMA)	-1,6-bis(methacryl-ethyloxy carbonylamino)trimethyl hexane (UDMA) -Nonamethylenediol dimethacrylate (ND)	
Physical property	Sensitivity to ambient light	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Similar but all devices conform to the requirements of ISO 4049 and therefore the subjected device is substantially equivalent.
	Depth of cure	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Flexural strength	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Water sorption	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Solubility	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Color stability	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Radio-opacity	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
Sterilization		Non-sterile	Non-sterile	Non-sterile	Identical
Shelf life		3 years at a temperature between 0-25ºC (32-77Fº)	3 years at a temperature between 0-25ºC (32-77Fº)	3 years at a temperature between 0-25ºC (32-77Fº)	Identical

Shelf Life Testing

Tokuyama tested the device to establish a shelf life of three years at a temperature between 0-25°C (32-77F°).

Material And Chemical Composition

The device does come into direct contact with the patient. However, all of the ingredients contained in OMNICHROMA FLOW BULK are used in Tokuyama Dental Corp.'s OMNICHROMA (K#173275), OMNICHROMA FLOW (K#193537), and ESTELITE FLOW QUICK High Flow (K#051808).

Performance Data Summary

Non-clinical testing of the physical properties of the OMNICHROMA FLOW BULK device was conducted in accordance with ISO 4049:2009, "Dentistry -- Polymer-based Restorative Materials." There were no clinical tests performed for the OMNICHROMA FLOW BULK device.

A comparison of the OMNICHROMA FLOW BULK device with the predicate devices shown below:

		Subject device	Predicate #1	Predicate #2	Difference
Device name		OMNICHROMA FLOW BULK	ESTELITE BULK FILL Flow	OMNICHROMA FLOW	-
Physical property	Sensitivity to ambient light	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Similar but all devices conform to the requirements of ISO 4049 and therefore the subjected device is substantially equivalent.
	Depth of cure	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Flexural strength	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Water sorption	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Solubility	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Color stability	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
	Radio-opacity	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	
Sterilization		Non-sterile	Non-sterile	Non-sterile	Identical
Shelf life		3 years at a temperature between 0-25ºC (32-77Fº)	3 years at a temperature between 0-25ºC (32-77Fº)	3 years at a temperature between 0-25ºC (32-77Fº)	Identical

Conclusion

Based on the non-clinical testing conducted of the physical properties of the OMNICHROMA FLOW BULK device in comparison to the predicate device identified above, and based on the biocompatibility of authorized devices with similar ingredients for the same use and additional biocompatibility testing, it is concluded that the OMNICHROMA FLOW BULK device is substantially equivalent to the predicate devices.