August 19, 2020

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

Re: K193537
Trade/Device Name: Omnichroma Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: May 21, 2020
Received: May 22, 2020

Dear Keith Barritt:

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 “Nandu” Nandkumar
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)*
K193537

Device Name
OMNICHROMA FLOW

Indications for Use *(Describe)*

The device is indicated for use for direct anterior and posterior restorations, cavity base or liner, and 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.

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510(k) Summary
Tokuyama Dental Corporation
OMNICHROMA FLOW
tooth shade resin material

Submitter

(i) 510(k) Submitter

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(ii) 510(k) Submitter Contact

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(iii) Preparation Date

August 14, 2020

Device

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

Predicate Device

Primary Predicate: Tokuyama Dental Corporation's OMNICHROMA (K#173275)
Reference Device: Tokuyama Dental Corporation's ESTELITE UNIVERSAL FLOW (K#180613)

Device Description

The OMNICHROMA FLOW tooth shade resin material is a paste that comes in a plastic syringe (1.8mL). The device is a low viscosity, light-cured, radiopaque composite resin for use in anterior and posterior restorations for all carious classes. OMNICHROMA FLOW is a single shade material. Direct placement of OMNICHROMA FLOW into a prepared cavity allows for easy handling.

OMNICHROMA FLOW is designed to be cured by either a halogen or LED curing-light with a wavelength of 400-500 nm. Be sure to light-cure OMNICHROMA FLOW extra-orally and check the time needed for complete hardening of OMNICHROMA FLOW with your light-curing unit before performing the bonding procedure.

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.

The OMNICHROMA FLOW device contains methacrylic monomers and a UV absorber. The device should not be used on patients who are allergic to or hypersensitive to methacrylic and related monomers, UV absorber, or any of the other ingredients.

Indications for Use

The device is indicated for use for direct anterior and posterior restorations, cavity base or liner, and repair of porcelain/composite.

Comparison of Technological Characteristics

The OMNICHROMA FLOW 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 device does not have its own energy source.

For purposes of performance characteristics for obtaining FDA marketing authorization, the OMNICHROMA FLOW device is substantially equivalent to Tokuyama's own primary predicate, the OMNICHROMA device (K#173275), as shown below:

		Subject device		Primary predicate	Reference	Difference
Device name		OMNICHROMA FLOW		OMNICHROMA	ESTELITE UNIVERSAL FLOW	-
Manufacturer		Tokuyama Dental		Tokuyama Dental	Tokuyama Dental	-
510(k) No.		K193537		K173275	K180613	-
Health Canada licence No.		(Pending)		101564	101263	
Classification name		Material, Tooth Shade, Resin		Material, Tooth Shade, Resin	Material, Tooth Shade, Resin	-
Indications for Use		- Direct anterior and posterior restorations - Cavity base or liner - Repair of porcelain/composite		For use as a tooth shade resin material in dental procedures, such as: - Direct anterior and posterior restorations - Direct bonded composite veneer - Diastema closure - Repair of porcelain/composite	- Direct anterior and posterior restorations - Cavity base or liner - Blocking out cavity undercuts before fabricating indirect restorations - Repair of porcelain/composite	Similar The indications for Use of subject device is within that of the predicate and reference devices.
Component		Container	Syringe or Pre-loaded tip	Syringe or Pre-loaded tip	Syringe or Pre-loaded tip	Identical
		Shade	1 shade	1 shade	12 shade	Similar The number of shades of the 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) - Nonamethylenediol dimethacrylate (ND)		- 1,6-bis(methacryl-ethyloxy carbonylamino)trimethyl hexane (UDMA) - Triethylene glycol dimethacrylate (TEGDMA)	- Bisphenol A polyethoxy methacrylate (Bis-MPEPP) - Bisphenol A di(2-hydroxypropoxy) dimethacrylate (Bis-GMA) - Triethylene glycol dimethacrylate (TEGDMA) - 1,6-bis(methacryl-ethyloxy carbonylamino)trimethyl hexane (UDMA)	
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.

For purposes of material and chemical composition, the OMNICHROMA FLOW device has the same basic characteristics as Tokuyama's own OMNICHROMA (K#173275) and ESTELITE UNIVERSAL FLOW (K#180613).

Additional biocompatibility assessment included cytotoxicity, sensitization, oral mucosa irritation, subacute systemic toxicity, acute systemic toxicity, and genotoxicity testing.

Performance Data Summary

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

Comparison of OMNICHROMA FLOW device with the primary predicate and reference device:

		Subject device	Primary predicate	Reference	Difference
Device name		OMNICHROMA FLOW	OMNICHROMA	ESTELITE UNIVERSAL 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 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 device is substantially equivalent to the predicate device.

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