February 27, 2018

Tokuyama Dental Corporation
% Keith Barritt
Fish & Richardson P.C.
901 15th Street, Suite 700
Washington, District of Columbia 20005

Re: K173275
Trade/Device Name: OMNICHROMA
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: November 28, 2017
Received: November 29, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Andrew I. Steen -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)*
K173275

Device Name

OMNICHROMA

Indications for Use *(Describe)*
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

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 dental resin material

Submitter

(i) 510(k) Submitter

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(iii) Preparation Date

February 26, 2018

Device

Trade or Proprietary Name:	OMNICHROMA
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 PALFIQUE ESTELITE LV CLEAR (K#010267).

Reference Devices: Kuraray's CLEARFIL MAJESTY ES-2 (K#121583); Heraeus Kulzer's VENUS PEARL (K#112501); Tokuyama Dental Corporation's ESTELITE SIGMA QUICK (K#080940); Tokuyama Dental Corporation's ESTELITE FLOW QUICK (K#051808); and Tokuyama Dental Corporation's ESTELITE BULK FILL FLOW (K#161353)

Device Description

The OMNICHROMA device is a light-cured, radiopaque composite resin for use in anterior and posterior restorations and is indicated for all carious classes. The OMNICHROMA device is available in only one shade.

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
- Direct bonded composite veneer
- Diastema closure
- Repair of porcelain/composite

Comparison of Technological Characteristics

The OMNICHROMA device does not have its own energy source. There are no accessories provide with the device. The OMNICHROMA device has the same basic technological characteristics in terms of design, material, and chemical composition as the primary predicate device as shown below:

Comparison of OMNICHROMA device with the primary predicate device

		Subject device	Primary predicate	Difference
Device name		OMNICHROMA	Palfique Estelite LV Clear	-
Manufacturer		Tokuyama Dental	Tokuyama Dental	-
510(k) No.		K173275	K010267	-
Classification name		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 - Direct bonded composite veneer - Diastema closure - Repair of porcelain/composite	For use as a tooth shade resin material in dental procedures.	Indications for new device are within those of the predicate
Component	Container	Syringe or Pre-loaded tip	Syringe	Use of pre-loaded tip
	Shade	1 shade	1 shade	
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)	

Material	Filler	- Silica-zirconia filler - Composite filler	- Silica-titania filler	As all of the ingredients in the subject device have already been authorized by FDA for use in similar devices
	Resin matrix monomer	- 1,6-bis(methacryl-ethyloxy carbonylamino)trimethyl hexane (UDMA) - Triethylene glycol dimethacrylate (TEGDMA)	- Methacrylates	
Physical property	Sensitivity to ambient light	Conformed to the requirement of ISO 4049	Conformed to the requirement of ISO 4049	Conformance to standard; specific measurements may vary slightly
	Depth of cure	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	
	Flexural strength	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	
	Water sorption	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	
	Solubility	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	
	Color stability	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	
	Radio-opacity	Conformed to the requirement of ISO 4049 Dentistry -- Polymer-based restorative materials	-	
Sterilization		Non-sterile	Non-sterile	

Performance Data Summary

Non-clinical testing of the physical properties of the OMNICHROMA device was conducted in accordance with ISO 4049:2009, which specifies requirements for dental polymer-based restorative materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of cavities in the teeth and for luting. The polymer-based luting materials covered by ISO 4049:2009 are intended for use in the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges.

There were no clinical tests performed for the OMNICHROMA device.

Conclusion

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

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