DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Tokuyama Dental Corporation
% Keith Barritt
Official Correspondent
Fish & Richardson P.c.
1425 K Street, N.W., Suite 1100
Washington, District of Columbia 20005

April 3, 2017

Re: K161353
Trade/Device Name: Estelite Bulk Fill Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: March 2, 2017
Received: March 3, 2017

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161353

Device Name
ESTELITE BULK FILL Flow tooth shade resin

Indications for Use *(Describe)*

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

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
ESTELITE BULK FILL Flow
tooth shade resin material

The following information is provided pursuant to 21 CFR 807.92.

Submitter

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(iii) Preparation Date

October 13, 2016

Device

Trade or Proprietary Name:	ESTELITE BULK FILL Flow
Common Name:	tooth shade resin material
Classification Name:	material, tooth shade, resin
Class:	2
Product Code:	EBF

Predicate Device

For purposes of performance characteristics for obtaining FDA marketing authorization, the ESTELITE BULK FILL Flow device is substantially equivalent to Tokuyama's own primary predicate ESTELITE FLOW QUICK (K#051808), as shown below:

Device name	ESTELITE BULK FILL Flow	ESTELITE FLOW QUICK
Sensitivity to ambient light	Upon visual inspection, the material remained physically homogenous (A3)	Upon visual inspection, the material remained physically homogenous (A3)
Depth of cure(1) (mm)	4.0 ± 0.1 (Universal) 3.6 ± 0.1 (A3)	2.0 ± 0.1 (A3)
Flexural strength)MPa)(1)	146 ± 4 (A3)	152.5 ± 20.2 (A3)
Water sorption(1) ($\mu g/mm^3$)	22.5 ± 0.5 (A3)	9.0 ± 0.1 (A3)
Solubility(1) ($\mu g/mm^3$)	0.6 ± 0.3 (A3)	0.6 ± 0.2 (A3)
Shade(1)	Upon visual inspection, the shade of the set material matched closely that of a shade guide (A3)	Upon visual inspection, the shade of the set material matched closely that of a shade guide (A3)
Color stability(1)	Upon visual inspection, no more than a slight change in color was observed (A3)	Upon visual inspection, no more than a slight change in color was observed (A3)
Radio-opacity (mm of Al)(1)	1.7 (A3)	1.2 (A3)
Compressive strength(1) (MPa)	371 ± 10 (A3)	375 ± 26 (A3)
Elastic modulus(1) (GPa)	7.5 ± 0.1 (A3)	8.8 ± 0.4 (A3)
Surface hardness(1) (Hv)	35 (A3)	44 (A3)

(1) In these evaluation items, the cured material of each device was used as test specimen. The condition to cure each device was as follows:

Device	Intensity for curing	Curing time	Wavelength
ESTELITE BULK FILL Flow	800 mW/cm^2	10 sec	Using light-curing unit with a wavelength of 400-500 nm
ESTELITE FLOW QUICK	800 mW/cm^2	10 sec	

Other similar reference devices are ESTELITE FLOW QUICK High Flow (also cleared under K#051808), FILTEK BULK FILL FLOWABLE RESTORATIVE (K#120453), and the nuance FLOW tooth shade resin material (K#143679). As shown above, the K#051808 and K#120453 devices demonstrate that certain characteristics of the subject device that are not included in the ISO 4049:2009 recognized standard but that are included in the FDA's 2005 guidance on Dental Composite Resin Devices are within the norm of similar legally marketed devices. Furthermore, K#120453 is cleared for use as a "liner under direct restorative materials," which is essentially the same as the "cavity liner" indication for Tokuyama's ESTELITE BULK FILL Flow tooth shade resin subject device.

A further chart comparing Tokuyama's ESTELITE BULK FILL Flow tooth shade resin subject device with the ESTELITE FLOW QUICK primary predicate K#051808 and the reference devices K#120453 and K#143679 appears on the following two pages.

Comparison with the primary predicate and the reference devices

	Subject device	Primary predicate	Reference		Difference
Trade name	ESTELITE BULK FILL Flow	ESTELITE FLOW QUICK	Filtek Bulk Fill Flowable Restorative	Nuance FLOW	-
Manufacturer	Tokuyama Dental Corporation	Tokuyama Dental Corporation	3M ESPE Dental Products	Den-Mat Holdings, LLC	-
510(k) No.	(Pending)	K051808	K120453	K143679	-
Classification name	Material, Tooth Shade, Resin	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 lining, -Blocking out cavity undercuts before fabricating indirect restorations, -Repair of porcelain/composite materials.	For use as a tooth shade resin material in dental procedures	- Base under Class I and II direct restorations - Liner under direct restorative materials - Pit and fissure sealant - Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations) - Class III and V restorations - Undercut blockout - Repair of small enamel defects - Repair of small defects in esthetic indirect restorations - Repair of resin and acrylic temporary materials - As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown	Nuance FLOW is recommended for the following types of applications: 1) Direct restorations of anterior or posterior teeth 2) Cavity base/liner 3) Intraoral repairs of fracture crowns/bridges	Similar The Indications for Use of subject device is within that of the predicate and the 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)	Tooth shade resin material that is cured by photo polymerization. (Light-cure)	Similar

Material	-Silica-zirconia filler -Composite filler -Bis-GMA -TEGDMA -Bis-MPEPP -Photo-polymerization initiator	-Silica-zirconia filler -Silica-titania filler -TEGDMA -Bis-MPEPP -UDMA -Photo-polymerization initiator	-Zirconia/silica filler -Ytterbium trifluoride filler -Bis-GMA -UDMA -Bis-EMA(6) -Procrylat -Photo-polymerization initiator	-Silanated barium glass filler -Silanated colloidal silica -Bis-GMA -Photo-polymerization initiator	Similar The subject device contains a filler, methacrylic monomer and photo-polymerization initiator as with the predicate and the reference devices.
Physical properties					
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	Conformed to the requirement of ISO 4049	Similar
Depth of cure	Conformed to the requirement of ISO 4049	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	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	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	-	
Shade	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	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	Conformed to the requirement of ISO 4049	

For purposes of biocompatibility, the ESTELITE BULK FILL Flow device is substantially equivalent to Tokuyama's own TOKUYAMA BOND FORCE (K#070215), ESTELITE FLOW QUICK (K#051808), and ESTELITE COLOR (K#110178), as all ingredients in the ESTELITE BULK FILL Flow device have been cleared for marketing by the FDA for use in these similar devices.

Device Description

ESTELITE BULK FILL Flow is a low viscosity, light cured radiopaque composite dental tooth shade resin material. This low stress flowable material can be placed in 4 mm increments. The device incorporates Radical-Amplified Photopolymerization (RAP) initiator technology, which facilitates a shortened light curing time and ample working time. The device comes in five shades, namely U (Universal), A1, A2, A3, and B1.

Biocompatibility testing is not required because all the ingredients in the ESTELITE BULK FILL Flow device have already been authorized by the FDA for use in similar devices and Tokuyama Dental Corporation has received almost no complaints of personal adverse effects of any kind (and no serious injury) involving the ingredients used in the ESTELITE BULK FILL Flow device.

The device does not come sterilized and is not intended to be sterilized prior to use.

Indications for Use

The ESTELITE BULK FILL Flow device is indicated 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

Comparison of Technological Characteristics

The ESTELITE BULK FILL 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 ESTELITE BULK FILL Flow device does not have its own energy source.

For purposes of material and chemical composition, the ESTELITE BULK FILL Flow device has the same basic characteristics as Tokuyama's own Tokuyama's own TOKUYAMA BOND FORCE (K#070215), ESTELITE FLOW QUICK (K#051808), and Estelite Color (K#110178).

Performance Data Summary

Non-clinical testing of the physical properties of the ESTELITE BULK FILL Flow device was conducted in accordance with ISO 4049:2009. There were no clinical tests performed for the ESTELITE BULK FILL Flow device.

The device does come into direct contact with the patient. All of the ingredients in the ESTELITE BULK FILL Flow device have been authorized by the FDA for use in similar Tokuyama devices. Thus, under Section 6 of ISO 10993-1, no further biocompatibility testing is required.

The ingredients in the ESTELITE BULK FILL Flow device are the same as in three of Tokuyama's own previously authorized devices, namely TOKUYAMA BOND FORCE (K#070215), ESTELITE FLOW QUICK (K#051808), and ESTELITE COLOR (K#110178). These devices have been used for many years without any reportable incidents to local health authorities and for which almost no complaints have been received regarding personal adverse effects of any kind and no serious injuries.

Conclusion

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