



Food and Drug Administration
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July 21, 2015

Ultradent Products, Inc.
Ms. Karen Kakunes, RN
Sr. Regulatory Affairs Associate
505 West 10200 South
South Jordan, UT 84095

Re: K151094
Trade/Device Name: Mosaic™ Universal Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF
Dated: April 22, 2015
Received: April 23, 2015

Dear Ms. Kakunes:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151094

Device Name

Mosaic Universal Composite

Indications for Use (Describe)

Mosaic is used for direct and indirect restorations (inlays, onlays, and veneers) in both the anterior and posterior regions.

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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Section 5: 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Karen Kakunes, RN
Title:	Sr. Regulatory Affairs Associate
Telephone:	800-552-5512 x4420, 801-553-4366
FAX:	801-553-4609
Date Summary Prepared:	17 Jul 2015

II. Name of the Device

Trade Name:	Mosaic™ Universal Composite
Common Name:	Tooth Shade Resin Material
Device Classification:	II
Classification Product Code:	EBF
Regulation No.	21 CFR 872.3690

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

Mosaic is substantially equivalent to Filtek™ Supreme Ultra Universal Restorative (K083610) and 3M™ Dent II System (K981647), both of which have been cleared under dental device product code EBF (tooth shade resin material). Mosaic is substantially similar to the predicate devices in Indications for Use, chemical composition, mechanical and physical properties, and application.

IV. Device Description:

Mosaic is a light-cured, bisGMA-based universal restorative composite. Mosaic is radiopaque and available in multiple shades. It has a nano-hybrid composite containing zirconia-silica glass ceramic and 20 nanometer silica. Filler load is 68% by volume for the dentin shades and 56% for the enamel shades. Mosaic is supplied in multi-use syringes (4.0 grams) and single compules (0.2 grams).

V. Statement of intended use:

Mosaic is used for direct and indirect restorations (inlays, onlays, and veneers) in both the anterior and posterior regions.

VI. Indication of Risk Analysis Method:

Risk Analysis was performed on Mosaic utilizing processes based on ISO 14971:2012. Risks associated to patient safety and product efficacy for Mosaic have been identified, assessed, and controlled to level that is as low as currently feasible. Any remaining residual risks are not considered to be hazardous to patients, customers, and/or end users. Ultradent considers Mosaic to be substantially equivalent in safety and effectiveness in its intended use as compared to the predicate device.

VII. Technological Characteristics and Testing Summary:

The technological characteristics of Mosaic are very similar to those of the predicate devices, 3M™ Dent II System (K981647) and Filtek™ Supreme Ultra Universal Restorative (K083610). Mosaic is a similar product, manufactured with similar or identical materials and used in the same way by the same types of users.

Mosaic has been tested and designed in accordance with ISO 4049:2009 Dentistry – Polymer-based restorative materials. Biocompatibility testing has been assessed according to EN ISO 10993-1:2009.

The device design, delivery form(s) and intended use of Mosaic and the predicate devices are the same or very similar. Based on the technological characteristics and performance testing, Mosaic has demonstrated it is substantially equivalent to the identified predicate device(s).

Table 5-1: Substantial equivalence comparison

Characteristic	Comparison Product (3M Dent II System K981647)	Comparison Product (Filtek Supreme Ultra Universal Restorative K083610)	Mosaic Universal Composite
Intended Use	Direct anterior and posterior restorations including: <ul style="list-style-type: none"> • Class III, IV, V, and VI • Veneers • Incisal edge repair Direct posterior restorations including: <ul style="list-style-type: none"> • Class I or II • Sandwich technique with glass ionomer resin material • Cusp buildups Core Buildups Splinting Indirect anterior and posterior restoration including: <ul style="list-style-type: none"> • Inlays • Onlays • Veneers 	Filtek Supreme Ultra universal restorative is indicated for use in: <ul style="list-style-type: none"> • Direct anterior and posterior restorations (including occlusal surfaces) • Core Build-ups • Splinting • Indirect restorations including inlays, onlays and veneers 	Mosaic is used for direct and indirect restorations (inlays, onlays, and veneers) in both the anterior and posterior regions.
Intended user	Licensed dentist	Licensed dentist	Licensed dentist
Chemical Characteristics	Bis-GMA	Bis-GMA, UDMA, TEGDMA, PEGDMA, and Bis-EMA resins	Bis-GMA based resin
Delivery system	Unknown	Capsule, syringe	Compule, syringe
Physical properties	36 month shelf life, room temperature Radiopaque Light Cure System	36 month shelf life, room temperature Available in a variety of VITA Shades Radiopaque Enamel shade: 63.3% Filled by Volume; Translucent shade: 55.6% Filled by Volume	24 month shelf life, room temperature Available in a variety of VITA Shades Radiopaque Dentin shade: 68% Filled by Volume; Enamel shade: 56% Filled by Volume Light Cure System

		Light Cure System	
Biocompatibility	ISO 10993	ISO 10993	Cytotoxicity, Genotoxicity, Delayed-Type Hypersensitivity, Irritation
Functional Testing	ISO 4049	ISO 4049:2009	ISO 4049:2009