March 15, 2024

Ultradent Products, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K240694
Trade/Device Name: FORMA Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: March 12, 2024
Received: March 14, 2024

Dear Dave Yungvirt:

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240694

Device Name
FORMA Composite

Indications for Use *(Describe)*
FORMA Composite is designed for restorations in anterior and posterior teeth.

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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Ultradent Products, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095
Est. Reg. No. 1718912

510(k) Summary

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

I. Applicant's Name and Address

Ultradent Product, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Contact Person:	Adam Black
Title:	Senior Manager – Regulatory Affairs
Telephone:	801-553-4425
Email:	adam.black@ultradent.com
Date Summary Prepared:	March 11, 2024

II. Name of the Device

Device:	FORMA Composite
Trade/Device Name:	FORMA Composite (Shade A3D)
Common Name:	Tooth Shade, Resin
Review Panel:	Dental
Regulation Number:	21 CFR 872.3690
Device Class:	Class II
Product Code(s):	EBF

III. Device Description

FORMA™ Composite is a Bis-GMA-based restorative composite. FORMA™ composite is designed for restorations in anterior and posterior teeth and is suitable for occlusal surfaces. Its formula contains a zirconia/silica inorganic filler combination and barium glass. FORMA™ composite is shaded based on the VITA shade guide, and is radiopaque. FORMA™ composite has a radiopacity value greater than 2 mm of aluminum. Aluminum has a radiopacity equivalent to that of dentin. Thus, 1 mm of material having a radiopacity equivalent to 1 mm of aluminum has a radiopacity equivalent to that of dentin and 2 mm of aluminum is equivalent to enamel.

FORMA™ composite A3D is filled 78% w/w. FORMA™ composite is a nanohybrid composite with nanoparticles entombed within the composite's formulation.

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IV. Statement of Intended Use

FORMA™ Composite is used for direct and indirect restorations in both the anterior and posterior regions.

V. Predicate Device

Predicate Identified: Mosaic Universal Composite K151094

VII. Comparison of Technological Characteristics

Predicate technological comparison:

The predicate and subject device have the same technological characteristics, which is primarily the design as a light-curable dental composite material which is available in a reusable syringe and single-use capsule presentation. The primary difference between the subject and predicate device is in the chemical composition which was adjusted for handling and shading. These differences and similarities have been evaluated below in Table 1:

Table 1

Descriptive Information	Subject Device: FORMA Composite	Predicate: Mosaic Universal Composite (K151094)	Explanation of Differences
Product Code	EBF	EBF	N/A – Identical product code
Indications for Use	FORMA™ Composite is used for direct and indirect restorations in both the anterior and posterior regions.	Mosaic composite is used for direct and indirect restorations (inlays, onlays, and veneers) in both the anterior and posterior regions.	The removal of the examples of indirect restoration types “inlays, onlays, and veneers” does not impact the safety or performance as this information was only to provide small clarification.
Principle of Operation	Mechanical leverage is used to express composite. The unique chemical structure of FORMA	Mechanical leverage is used to express composite. The unique chemical structure of Mosaic allows	N/A – Identical principles of operation

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Descriptive Information	Subject Device: FORMA Composite	Predicate: Mosaic Universal Composite (K151094)	Explanation of Differences
	Composite allows for the chemistry to be placed into preformed cavities in the tooth structure to rebuild the physical structure of the removed dentin. The formulation contains photoinitiators that cause polymerization of the moldable chemistry. Once the device is polymerized, it exhibits mechanical and physical behaviors similar to that of natural dentition.	for the chemistry to be placed into preformed cavities in the tooth structure to rebuild the physical structure of the removed dentin. The formulation contains photoinitiators that cause polymerization of the moldable chemistry. Once the device is polymerized, it exhibits mechanical and physical behaviors similar to that of natural dentition.	
Intended User	Dentist or dental professional	Dentist or dental professional	N/A – Identical Intended User
Delivery System	4g Reusable Syringe or 0.2g single-use capsule	4g Reusable Syringe or 0.2g single-use capsule	N/A – Identical delivery system offerings
Composition of Materials	Bis-GMA, TEGDMA, Bis-EMA, and UDMA base Photoinitiators (Camphorquinone) Silanated Glass Silica	Bis-GMA, TEGDMA, UDMA base Photoinitiators (Camphorquinone) Silanated Glass Silica	Similar – Base material has been adjusted for handling and to achieve proper shade.
Physical Properties	• Depth of Cure ≥1.5mm • Curable wavelength 385-515nm • Curing Intensity ≥800 mW/cm^2 • Curing Time 10s per layer, 20s final cure • Flexural Strength ≥80 MPa • Filler particle size 0.014-3µm • Water sorption ≤40 µg/mm^3 • Water solubility ≤7.5 µg/mm^3 • Radio-Opacity ≥1mm of Al • Surface Hardness ≥50.0 HK	• Depth of Cure ≥1.5mm • Curable wavelength 385-515nm • Curing Intensity ≥800 mW/cm^2 • Curing Time 10s per layer, 20s final cure • Flexural Strength ≥80 MPa • Filler particle size* ≥0.02µm • Water sorption ≤40 µg/mm^3 • Water solubility ≤7.5 µg/mm^3 • Radio-Opacity ≥1mm of Al • Surface Hardness ≥50.0 HK	Similar – ISO 4049 Compliant
FDA Recognized Standards	ISO 7405: 2018 ISO 4049:2019 IEC 62366-1:2020 ISO 14971:2019 ISO 10993-1:2018 ISO 15223-1:2021 ISO 7491:2000	ISO 7405: 2018 ISO 4049:2009 IEC 62366-1:2015 ISO 14971:2012 ISO 10993-1:2018 ISO 7491:2000	Similar – Addition of ISO 15223-1 based on use of symbols

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VIII Non-Clinical Performance Testing:

Verification and validation testing was performed to show that the subject device is substantially equivalent to the currently marketed predicate device, Mosaic Universal Composite. Full testing to ISO 4049:2019, surface hardness evaluation, drop test ship testing, and an assessment on the curing wavelength, curing intensity and curing time were completed for the product verification testing.

Simulated use and validation testing was conducted by dental professionals to confirm that all aspects from usability assessments and risk management were implemented in the labeling and the design of the device itself. The conclusion of this validation testing confirmed that the subject device met the predefined user needs and the indications for use, which are identical to the predicate device. Thus the verification and validation support the conclusion that the subject device, FORMA Composite, is substantially equivalent to the predicate device, Mosaic Universal Composite (K151094).

IX Biocompatibility Assessment

FORMA Composite has been evaluated for applicable biological risks associated to the device type according to ISO 7405:2018 and ISO 10993-1:2018. Cytotoxicity, Sensitization, and Irritation tests were conducted according to applicable ISO 10993 series standards. Other applicable biological endpoints (Systemic Toxicity, Implantation Effects, and Genotoxicity) were evaluated utilizing available literature, chemical characterization testing and other biocompatibility tests available for the device and its constituents.

Conclusion:

The predicate and subject devices have identical indications for use with a slight variation to remove the examples of indirect restoration types. The differences between the predicate and subject device have been evaluated with established methods, including testing to ISO 4049, biological risk evaluations according to ISO 10993-1, and product packaging assessments. Based on the testing and evaluation of the subject device, FORMA Composite, as compared to the predicate device, Mosaic Universal Composite (K151094), the conclusion can be made that FORMA Composite is substantially equivalent to the predicate device.