May 11, 2026

Vericom Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2552 Wanut Ave. Suite 230
Tustin, California 92780

Re: K260805
Trade/Device Name: Dual Core
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: March 11, 2026
Received: March 12, 2026

Dear Priscilla Chung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260805

Please provide the device trade name(s).

Dual Core

Please provide your Indications for Use below.

Core build-up

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K260805
510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___Mar 11, 2026___

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	Dual Core
Common Name:	Dual-cured composite resin
Classification Name:	Material, Tooth Shade, Resin (21 CFR 872.3690, Product Code: EBF)

4. Predicate Device:

Luxacore Dual (K012307) by DMG USA, INC.

5. Device Description:

Dual Core is a dual-cured (light and chemical), radiopaque compound used for replacing dental caries and core build-up. It comes in two types: cartridge and syringe. By attaching an intraoral tip, application to the treatment area becomes easier. Dual Core does not have a prior 510(k) clearance. The subject device is a new device.

6. Indications for Use:

Core build-up

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Shelf-Life Tests: Appearance, Shade, Working Time, Setting Time, Water Sorption, Solubility, Flexural Strength
- Performance Tests: Working Time, Setting Time, Flexural Strength, Water Sorption, Solubility, Shade, Color Stability, Radio-opacity, Compressive Strength, Flexural Modulus, Surface Hardness, Filler particle size distribution
- Biocompatibility Tests: Cytotoxicity (ISO 10993-5), Sensitization, GPMT (ISO 10993-10), Oral Mucosa Irritation (ISO 10993-23), Systemic toxicity / Oral (ISO 10993-11), Genotoxicity (ISO 10993-3)

8. Substantial Equivalence

8.1. Comparison Chart

	Subject Device	Primary Predicate Device
Trade Name	Dual Core	Luxacore Dual
Manufacturer	VERICOM CO., LTD.	DMG USA, INC.
510K Number	-	K012307
Product Code	EBF	EBF

Indications for Use	Core build-up	- The Principal use for LuxaCore a Dual is as a core material either with adhesive or with pins or posts. - Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials. - Repair material for provisionals - Bite registration material - Build up material for plastic bite rail (Occlusal individualization) - Cement for pins and posts - Semipermanent restorative material (e.g., in children's teeth)
Raw materials	- Barium aluminosilicate - Silica - Bis-GMA base matrix	- Barium glass - Pyrogenic silicic acid - Bis-GMA Based matrix
Principle of operation	This product is a dual-cured paste product consisting of monomer, filler, photoinitiator, base-catalyst reagent, accelerator and pigment in syringes and cartridges. The shape of the syringe and cartridge consists of two containers each in one form. Each container consists of a base and a catalyst, and the mixing & intraoral tip is attached to the front of the syringe or cartridge so that the base and catalyst are mixed before use and the product is discharged. In case of cartridge type, it is additionally used by attaching to the dispensing gun. After the product is discharged, the product is irradiated with light with a wavelength of 420-500nm, the photoinitiator and accelerator interact to initiate the monomer and cure the product. At this time, dual curing, which includes self-polymerization by chemical reaction with the base-catalyst, proceeds. If photopolymerization is not carried out, only self-polymerization by base-catalyst chemical reaction can proceed, but curing time may be further delayed. Through this mechanism, Dual core restores and build up carious lesions or structural defects of teeth.	LuxaCore Dual is an automatic mixing, dual-cure composite that has been specially developed for all types of core build-ups and build-up fillings. Radiopaque LuxaCore-Dual stands our due to its high compressive strength, and it cuts like dentine. The curing time can be self-determined due to additional light curing. It is possible to apply LuxaCore-Dual directly using the intraoral tips and the endo tips. The paste mixed though the tips applies for cavity for core build ups and build up fillings. The paste undergoes self-polymerization after mixed and can be also be photopolymerized by the light-curing unit. The light curing unit should have an output of 450nm and The light intensity should be a minimum of 400 ㎽/㎠. Place the light as close as possible to the material.
Performance Standard Conformance	Conformed to ISO 4049	Conformed to ISO 4049
Biocompatibility	Yes	Yes
Use	Prescription / Hospital	Prescription / Hospital
Setting time	Intraoral 4 minutes	Intraoral 5 minutes
Delivery Forms	Auto mixing of paste A and Paste B	Auto or hand mixing of paste A and Paste B

Sterility	Non-sterile	Non-sterile

8.2. Substantial Equivalence Discussion

Dual Core has the same intended use and principle of operation as the predicate device, Luxacore Dual (K012307) by DMG USA, INC. It also possesses similar physical and biocompatible properties, demonstrating comparable performance specifications.

The differences between Dual Core and the predicate device (Luxacore Dual) lie in the scope of indications for use and setting time. However, the predicate device (Luxacore Dual) has a broader scope of indications, and the indications for use of Dual Core are fully encompassed within those of the predicate device. Additionally, the setting times of both devices comply with the requirements of ISO 4049. Therefore, the difference in setting times is not clinically significant.

Bench and biocompatibility tests for Dual Core were conducted in accordance with recognized consensus standards applicable to the international standards (e.g., ISO 4049, ISO 10993), and the CDRH Guidance document (Docket Number: FDA-2020-D-0957). The test results meet the requirements outlined in these normative documents.

Based on the above, it can be concluded that Dual Core is substantially equivalent to the predicate device, Luxacore Dual.

9. Conclusion:

Based on the testing results, Vericom Co., Ltd. concludes that the Dual Core is substantially equivalent to the predicate devices.