October 15, 2024

Den-Mat Holdings, LLC
Kim Maynes
Sr. Supervisor, Regulatory Affairs
1017 W. Central
Lompoc, California 93436

Re: K242097
Trade/Device Name: DenMat Bulk Fill Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 17, 2024
Received: July 18, 2024

Dear Kim Maynes:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
ENT Devices
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Respiratory, ENT, and Dental Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242097

Device Name

DenMat Bulk Fill Composite

Indications for Use *(Describe)*

Direct restoration of Class I, II, III and V cavities (ideally Class I and II), base or liner, core build-ups.

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) Submission Summary - K242097

1. Submitter Information

Submitter's Name:	Den-Mat Holdings, LLC
Address:	1017 W. Central Avenue Lompoc, CA 93436
Phone Number:	805-346-3700
Contact Person:	Kim Maynes
Date of Summary Preparation:	7/17/24

2. Device Details

Device Name:	DenMat Bulk Fill
Device Classification Name:	Material, Tooth Shade, Resin
Common Name:	Composite Resin
Classification:	II
Regulation number:	21 CFR 872.3690
Classification Product Code:	EBF

3. Predicate Device

Submitter's device	**Predicate Device**	**Reference Device**
DenMat Bulk Fill	Name: Stela Automix Manufacturer: SDI Limited (Australia) 510(k) number: K222581	Name: DMRC Bulk Fill Manufacturer: Danville Materials LLC 510(k) number: K151088

4. Device Description

DenMat Bulk Fill is a tooth shaded, radiopaque, dual-cured (auto-cure with light-cure acceleration) composite that offers an unlimited depth of cure in a single application without multiple layers and light-curing when allowed to self-cure. DenMat Bulk Fill has the handling properties of a low viscosity or "flowable" composite that allows for adaptation to the prepared cavity walls. DenMat Bulk Fill is also ideal for core buildups, and any application where light transmission is inadequate. It is provided in multiple shades.

5. Indications for Use

Direct restoration of Class I, II, III and V cavities (ideally Class I and II), base or liner, core build-ups.

6. Comparison of Technological and Regulatory Characteristics with the Predicate Device

The similarities between DenMat Bulk Fill and the primary predicate Stela Automix and the reference device DMRC Bulk Fill, include the Regulatory Classification, Product Code, Intended Use of the device, Indications for Use, and Clinical condition of use. Furthermore, Technological Characteristics and Performance testing including Biocompatibility testing are similar.

There are no major differences but only minor differences between DenMat Bulk Fill and the primary predicate Stela Automix and the reference device DMRC Bulk Fill. Performance test results have slightly different values. In addition, the reference device, DMRC Bulk Fill, is a dual-cure bulk fill composite and uses identical curing light wavelength and curing time as DenMat Bulk Fill. The curing light intensity indicated for DMRC Bulk Fill is similar to DenMat Bulk Fill. These minor differences have no impact on the safety or performance of the device which demonstrates the subject device is substantially equivalent to the predicate device and the reference device.

Table 1 below compares DenMat Bulk Fill, the primary predicate Stela Automix and the reference device DMRC Bulk Fill with respect to intended use, technological characteristics and performance testing.

Non-clinical performance evaluations demonstrate that DenMat Bulk Fill is substantially equivalent to the primary predicate Stela Automix and the reference device DMRC Bulk Fill passes all standards, in terms of critical properties for restorative composites, including flexural and diametral strength, work time, set time, water solubility, water absorption and color stability.

Table 1.
Comparison of DenMat Bulk Fill, Primary Predicate Device and Reference Device

	Submitter's Device	**Primary Predicate Device**	**Reference Device**	**Comparisons**
Name	**DenMat Bulk Fill**	**Stela Automix**	DMRC Bulk Fill	
510(k) number	K242097	K222581	K151088	
Device Classification Name	Tooth Shade Resin Material	Tooth Shade Resin Material	Tooth shade resin material	Same
Regulation number	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3690	Same
Classification Product Code	EBF	EBF	EBF	Same
Indications for use	Direct restoration of Class I, II, III and V cavities (ideally Class I and II), base or liner, core build-ups.	1) Direct restoration of Class I, II, III and V cavities. Ideally Class I and II, 2) Base or liner, 3) Core build-ups	DMRC Bulk Fill is a dual-cure (auto-cure) with light-cure acceleration) polymer-based dental restoratives that when applied to dental surfaces pretreated with suitable primers or adhesives are indicated for use as the first increment under posterior composites; for core build-ups;	Same as the primary predicate

			and for luting posts, crowns, veneers and any application where light transmission may be inadequate	
Delivery System	Dual barrel syringe, with auto mixing tips	Dual barrel syringe, with auto mixing tips	Dual barrel syringe, with auto mixing tips	Same
Sterile	No	No	No	Same
Work time (seconds) (self cure)	105	130	90	Similar to predicate and reference
Set time (seconds) (self cure)	145	170	125	Similar to predicate and reference
Curing mechanism	Dual cure (self-cure and light-cure)	Self-cure	Dual cure (self-cure and light-cure)	Same as reference device
Curing light wavelength (nm)	400 - 500	N/A	400 - 500	Same as reference device
Curing time (seconds) (light cure)	10	N/A	10	Same as reference device
Curing light intensity (mW/cm^2)	> 1000	N/A	> 600 for halogen light and per manufacturing suggestions for LED lights	Similar to reference device
Flexural strength (MPa) (> 80)	119	137	118	Similar to predicate and reference
Diametral strength (MPa) (> 28)	52	56	54	Similar to predicate and reference
Water sorption ($\mu g/mm^3$) (< 40)	13	28	7	Similar to predicate and reference
Water solubility ($\mu g/mm^3$) (< 7.5)	0.1	-2.5	0.8	Similar to predicate

				and reference
Color stability	pass	pass	pass	Similar to predicate and reference
FDA Recognized Standards	ISO 4049 ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-18 ISO 10993-23 ISO 7405 ISO 14971 ISO 15223-1	ISO 4049 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-3 ISO 7405	ISO 4049	Similar to predicate and reference

7. Performance Testing

Biocompatibility assessment

According to *ISO 10993-1 Biological evaluation of medical devices —Part 1: Evaluation and testing within a risk management process,* the subject device is categorized as an external communicating device with contact to tissue/bone/dentin and is permanent contact device. DenMat Bulk Fill's chemical composition, as well as materials and technological properties, are substantially equivalent to those of FDA cleared commercial devices as defined in our assessment. Chemicals in DenMat Bulk Fill have been well documented and used extensively in the dental industry for many years. Clinical experience research reveals acceptable biocompatibility in devices in the same category (externally communicating devices for dental restorations) as DenMat Bulk Fill. Therefore, the combination of all materials, chemicals, and processes has an established history of safe use in the intended applications.

DenMat Bulk Fill has been submitted to the following biocompatibility tests and no significant adverse effects have been identified:

- Cytotoxicity
- Maximization Test for Delayed-Type Hypersensitivity
- Intracutaneous (Intradermal) Reactivity
- Bacterial Reverse Mutation Assay (Ames Test)
- In Vitro Mouse Lymphoma
- Pyrogen
- Implantation effects

Comparable dental devices with FDA clearance have not been a focus of any advisory notice or recalls from FDA that are related to biocompatibility issues.

In conclusion, DenMat Bulk Fill demonstrates acceptable biocompatibility for the intended use.

Non-clinical Performance Data:
The standards applicable to the submitter's device and the comparison of technological characteristics referenced include: *ISO 4049:2019 Polymer-Based Restorative Material; ANSI/ADA Standard No. 27-2016 Polymer-based Restorative Materials (Modified adoption of ISO 4049:2009, Dentistry — Polymer-based restorative materials); ISO 7491:2000 Dental materials — Determination of color stability; and DenMat internal testing methods*.

Non-clinical performance evaluations demonstrate that DenMat Bulk Fill is substantially equivalent to the primary predicate Stela Automix and the reference device DMRC Bulk Fill passes all standards in terms of critical properties for restorative composites, including flexural and diametral strength, work time, set time, water solubility, water absorption and color stability (reference Table 1).

Clinical Performance Data:
Clinical data is not needed to characterize performance and establish substantial equivalence. The nonclinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on the subject devices.

Electrical Safety and electromagnetic compatibility (EMC)
This section is not applicable.

Software verification and validation testing:
This section is not applicable.

Mechanical and Acoustic Testing:
This section is not applicable.

8. Conclusion Regarding Substantial Equivalence:

The performance and biocompatibility tests show DenMat Bulk Fill performs comparably to the predicate device and possesses a low likelihood of an unacceptable adverse biological response from contact of the component materials of the device with the body. The Denmat Bulk Fill indications for use are identical to the predicate device and are based on the same restorative materials technology. On this basis, DenMat Bulk Fill is substantially equivalent to the predicate device.