February 7, 2025

Mediclus Co., Ltd.
℅ Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, California 92612

Re: K242713
Trade/Device Name: Any-Com Bulk
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: January 8, 2025
Received: January 8, 2025

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 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242713

Device Name

Any-Com Bulk

Indications for Use *(Describe)*

- Base under Class I and Class II direct restorations
- Liner under direct restorative materials
- Restoration of small cavities
- Class III and V restorations
- 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
(K242713)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 1/7/2025

1. Submitter

MEDICLUS Co., Ltd.
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Cheongju-si, Chungcheongbuk-do, Republic of Korea
TEL : +82(43)211-2877 FAX : +82(43)211-2866

2. U.S Agent/Contact Person

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3. Device

- Trade Name: Any-Com Bulk
- Common Name: Tooth Shade Resin
- Classification Name: Tooth Shade Resin Material
- Product Code: EBF
- Classification regulation: 21 CFR 872.3690

4. Predicate Device:

3M Filtek Bulk Fill Flowable Restorative by 3M ESPE (K120453) (Primary predicate)

5. Description:

Any-Com Bulk is a light cured, radiopaque, flowable restorative material for both posterior and anterior restorations. It is designed to be used as a base-liner for Class I and II restorations. The product allows a technique in which a cavity up to 4mm in depth can be filled and cured in a single increment.

The product offers 5 shades options available. Users can select shades such as A1, A2, A3, TL and Blue, based on the desired brightness, yellowness, and darkness that match the

patient's natural teeth.

After the appropriate tooth pretreatment process, fill the appropriate amount of product to applying area. Once light cured, the composite can be finished and polished using conventional finishing and polishing instruments.

6. Indication for use:

- Base under Class I and Class II direct restorations
- Liner under direct restorative materials
- Restoration of small cavities
- Class III and V restorations
- Core build-ups

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device	Equivalence evaluation
510K#	K242713	K120453	
Manufacturer	MEDICLUS Co., Ltd.	3M ESPE	-
Product Name	Any-Com Bulk 	3M Filtek Bulk Fill Flowable Restorative 	-
510k#	-	K120453	-
Product Code	EBF	EBF	
Material	Bis-GMA UDMA TEDMA Ba-Glass Camphorquinone ▪ Inorganic filler loading is approximately 66% by weight ▪ particles size : 0.1~2.0 ㎛	Bis-GMA UDMA BisEMA Procrylat resins ▪ Inorganic filler loading is approximately 64.5% by weight ▪ Particle size : 0.1 to 5.0 ㎛	Similar
Curing type	Light Curing	Light Curing	Same
Indications for Use Statement	• Base under Class I and Class II direct restorations • Liner under direct restorative materials • Restoration of small cavities • Class III and V restorations • Core build-ups	• Base under Class I and 11 direct restorations • Liner under direct restorative materials • Pit and fissure sealant Restoration of minimally invasive cavity preparations (including	Same

			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	
Technological Characteristics	Standard	ISO 4049	ISO 4049	Same
	Curing Depth	3.5 mm	4 mm	
	Flexural strength	100 Mpa	126.5 Mpa	
	Water Absorption	30 μg/㎟	-	
	Solubility	0.6 μg/㎟	-	
	Radiopacity	over-2.9 mm	2.4 mm	
	Color and color stability	All samples have a matching shade guide	-	
	Sensitivity to ambient light	All samples are physically homogeneous	-	
Biocompatibility	Using ISO 10993 series Biocompatible		Using ISO 10993 series Biocompatible	Same
Delivery method	• Delivery System: Syringe • Weight: 2g • Units per Pack: 1, 2, 3 • Accessories: Tip		• Delivery System: Syringe • Weight: 2g • Units per Pack: 2 • Accessories: Tip	
Shade	A1, A2, A3, Blue, TL		A1, A2, A3, Universal	
Shelf-Life	3 years		3 years	Same

7.2. Comparison Chart

The subject device has the same indications for use and the technological characteristics as the predicate device. The minor raw materials are different between the devices but the performance and the biocompatibility test results show that it does not raise a concern in safety and effectiveness.

8. Non-Clinical Testing

- Performance Tests including Appearance, Weight, Packaging, Sensitivity to Ambient Light, Curing Depth, Flexural Strength, Water Sorption/Solubility, Color and Color stability, Radiopacity in accordance with ISO 4049
- Biocompatibility Tests

No	Test Item	Test Standard
1	Cytotoxicity	ISO 10993-5
2	Sensitization	ISO 10993-10
3	Irritation or Intracutaneous Reactivity	ISO 10993-10
4	Acute Systemic Toxicity	ISO 10993-11
5	Material-Mediated Pyrogenicity	BIOLOGICAL SAFETY ASSESSMENT REPORT
6	Subacute/Subchronic Toxicity	
7	Genotoxicity	
8	Implantation	
9	Chronic Toxicity	
10	Carcinogenicity	

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.