September 26, 2024

Mediclus Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc
18881 Von Karman, STE 160
Irvine, California 92612

Re: K241147
Trade/Device Name: Any-Com
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 1, 2024
Received: July 3, 2024

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,

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241147

Device Name
Any-Com

Indications for Use *(Describe)*

- Anterior and posterior restorations
- Core build-up
- Indirect restorations for inlays, onlays and veneers.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid 0MB number."

510(k) Summary

(K241147)

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

Date: ___Jun 24, 2024___

1. Applicant / Submitter:

MEDICLUS CO., LTD.
No. 1210, 134 Gongdan-ro, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Republic of Korea
Tel : +82-43-211-2877
Fax : +82-43-211-2866

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	Any-Com
Common Name:	Dental Composite Resin
Classification Name:	Tooth shade resin material
Classification:	Class II, 21 CFR 872.3690
Classification Product Code:	EBF

4. Predicate Device:

3M Filtek Universal Restorative (K183476) by 3M ESPE Dental Products

5. Device Description:

Any-Com is a composite resin material designed for use in anterior and posterior restorations.

It is composed of an enhanced zirconia filler, and all shades of the material are radiopaque. It is conveniently packaged in a syringe with a wide caliber. Dentists can dispense the material using their own instruments and apply it to the tooth.

The product offers a wide range of options with a total of 20 shades available. Dentists can select shades such as A1, A2, B1, B2, etc., based on the desired brightness, yellowness, and darkness that match the patient's natural teeth.

After the appropriate tooth pretreatment process for the selected shade, Any-Com is applied to the teeth using suitable instruments and in the appropriate amount. Once applied, it is permanently bonded to the tooth structure by using a photopolymerizer owned by the dentist for photocuring.

6. Indications for Use:

- Anterior and posterior restorations
- Core build-up
- Indirect restorations for inlays, onlays and veneers.

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.

- Appearance
- Capacity
- Package
- Sensitivity to Ambient Light
- Polymerization Depth
- Flexural Strength
- Water Absorption
- Solubility
- Color
- Color Stability
- Radioactive Impermeable

8. Substantial Equivalence

8.1. Comparison Chart

	Subject Device	Primary Predicate Device
Trade name	Any-Com	3M Filtek Universal Restorative
Manufacturer	MEDICLUS Co.,Ltd	3M ESPE Dental Products
510K Number	K241147	K183476
Product Code	EBF	EBF
Indications for Use	▪ Anterior and posterior restorations ▪ Core build-up ▪ Indirect restorations for inlays, onlays and veneers.	▪ Direct anterior and posterior restorations (including occlusal surfaces) ▪ Core build-ups ▪ Splinting ▪ Indirect restorations including inlays, onlays, and veneers
Image		
Raw materials	Methacrylate-based resin matrix, Inorganic fillers etc.	Methacrylate-based resin matrix, Inorganic fillers etc.
Principle of operation	When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.
Performance Standards Conformance	Conformed to ISO 4049	Conformed to ISO 4049
Biocompatibility	Yes	Yes
Use	Prescription / Hospital	Prescription / Hospital
Delivery form	Single paste	Single paste / Capsules

Light Curing Specification	- Curing time of 600~1,000 ㎽/㎠ stand curing unit : 20sec - Curing time of 1,000~1200 ㎽/㎠ stand curing unit : 10sec	- Curing time of 550~1,000 ㎽/㎠ stand curing unit : 20sec - Curing time of 1,000~2,000 ㎽/㎠ stand curing unit : 10sec

8.2. Substantial Equivalence Discussion

Any-Com is substantially equivalent to a predicate device, 3M Filtek Universal Restorative (K183476), by 3M Filtek Universal Restorative in terms of indications for use, base raw material, physical properties and technological characteristics. Both Any-Com and 3M Filtek Universal Restorative are ready-to-use paste.

The differences between Any-Com and 3M Filtek Universal Restorative are raw materials. However, performance tests in accordance with ISO 4049 and biocompatibility tests in accordance with ISO 10993 demonstrate that this difference does not raise a question in safety and effectiveness.

Based on the information we provided herein, we conclude that Any-Com is substantially equivalent to the predicate device.

9. Conclusion:

Based on the information submitted herein, MEDICLUS CO., LTD. concludes that the Any-Com is substantially equivalent to the predicate device.