June 6, 2025

Mediclus Co., Ltd.
Ku Da Hyeon
RA Associate
No. 1210, 134, Gongdan-ro, Heungdeok-gu
Cheongju-si, 28576
Korea, South

Re: K251283
Trade/Device Name: Once-Fil Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: April 25, 2025
Received: April 25, 2025

Dear Ku Da Hyeon:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251283

Device Name
Once-Fil Flow

Indications for Use *(Describe)*
- Temporary inlay and onlay treatments of the cavity.
- Sealing of openings for implant screws.
- Relining material for temporary crowns and bridges.
- Covering of the gingival margin
- Fixing of resin matrix during filling placement.
- Block-out material for retentive ares in the dental arch, e.g. before taking impressions.

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
(K251283)

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

Date: Apr 25,2025

1. Submitter/Contact Person

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3. Device

- Trade Name: Once-Fil Flow
- Common Name: Tooth Shade Resin
- Classification Name: Tooth Shade Resin Material
- Product Code: EBF
- Classification regulation: 21 CFR 872.3690

4. Predicate Device:

Clip Flow by VOCO GmbH (K153493)

5. Description:

Once-Fil Flow is a light-curing filling material designed for temporary restorations. It serves as an interim solution before the placement of a final prosthesis, providing

functions such as pulp protection and maintaining tooth position. The material is suitable for temporary fillings in prepared cavities and inlay/onlay cases.

To accommodate different clinical needs, Once-Fil Flow is available in two shades. The Yellow shade is ideal for anterior teeth, where esthetics are a priority, while the Blue shade provides clear visual contrast, making it easier to identify and remove before permanent restoration.

The application process involves preparing the tooth surface, applying an appropriate amount of material, and light-curing it. Once cured, the material can be finished and polished using conventional instruments.

6. Indication for use:

- Temporary inlay and onlay treatments of the cavity
- Sealing of openings for implant screws
- Relining material for temporary crowns and bridges
- Covering of the gingival margin
- Fixing of resin matrix during filling placement
- Block-out material for retentive areas in the dental arch, e.g. before taking impressions

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device	Equivalence evaluation
Manufacturer	MEDICLUS Co., Ltd.	VOCO GmbH	-
Product Name	Once-Fil Flow 	Clip Flow 	-
510k#	-	K153493	-
Product Code	EBF	EBF	
Material	Bis-GMA UDMA HEMA Silicone dioxide Camphorquinone 2,6-Di-tert-butyl-4-methylphenol (BHT) $CoAl_2O_4$ (Pigment) Etc..	BHT 2-hydroxyethyl methacrylate Urethane Methacrylate Pyrogenic silicic acids catalyst	Similar

Curing type		Light Curing	Light Curing	Same
Indications for Use Statement		1) Temporary inlay and onlay treatments of the cavity. 2) Sealing of openings for implant screws. 3) Relining material for temporary crowns and bridges. 4) Covering of the gingival margin. 5) Fixing of resin matrix during filling placement. 6) Block-out material for retentive areas in the dental arch, e.g. before taking impressions.	1) Temporary inlay and onlay treatments of the cavity. 2) Sealing of openings for implant screws. 3) Relining material for temporary crowns and bridges. 4) Covering of the gingival margin. 5) Fixing of resin matrix during filling placement. 6) Block-out material for retentive areas in the dental arch, e.g. before taking impressions.	Same
Intended User		Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Technological Characteristics	**Standard**	ISO 4049	ISO 4049	Similar
	Curing Depth	4.3 mm	4 mm	
	Water Absorption	32 μg/㎣		
	Solubility	5 μg/㎣	18.4 μg/㎣	
	Color and color stability	All samples have a matching shade guide	-	
	Sensitivity to ambient light	All samples are physically homogeneous	-	
	Shore D Hardness	Standard: ISO 868 Result: 53	-	
Biocompatibility		Biocompatible	Biocompatible	Same
Delivery method		• Delivery System: Syringe • Weight: 1.2ml • Disposable tip	• Delivery System: Syringe • Weight: 1.8g • Disposable tip	Similar
Period of Use		Prolonged exposure(B) (exceed 24 hours but not 30 days)	Prolonged exposure(B) (exceed 24 hours but not 30 days)	Same
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, Water Sorption/Solubility, Color and Color stability, Shore D Hardness in accordance with ISO 4049, ISO 868.

- Biocompatibility Tests
  - ISO 10993-1 Biological evaluation of medical devise – Part 1: Evaluation and testing within a risk management process
  - ISO 10993-5:2009, test for in vitro cytotoxicity
  - ISO 10993-21:2021, Tests for irritation
  - ISO 10993-11:2017, Tests for systemic toxicity
  - ISO 10993-10:2021, Tests for skin sensitization

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.