May 23, 2025

DSI Dental Solutions Ltd
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030

Re: K250778
Trade/Device Name: Sil-Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: February 11, 2025
Received: March 14, 2025

Dear Angela Blackwell:

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,

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)*
K250778

Device Name
Sil-Flow

Indications for Use *(Describe)*
Sil-Flow is indicated for

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

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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"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 OMB number."

Sil-Flow
510(k) Summary
February 11, 2025

Name and Address: DSI Dental Solutions Ltd
59 haAvoda St
Light Industrial Zone
Ashdod Israel 7706300
Contact Person: Shlomi Krasner
Email: info@dsisrael.com
Telephone: US Phone 972-200-3265

Name of device: Sil-Flow
Classification Name: Tooth Shade Resin Material
CFR: 21 CFR 872.3690
Primary Product Code: EBF
Regulatory Class: II

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description:

Sil-Flow is a flowable light-cured temporary filling material used for filling and sealing.

Indications for Use:

Sil-Flow is indicated for

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

Testing Summary: Sil-Flow was tested for visual appearance, depth of cure, Shor hardness D, sensitivity to ambient light, water sorption, water solubility, color stability, shade stability according to protocols based on ISO 4049.

All test results met the criteria in the standard.

Shelf life for Sil-Flow is 3 years. All shelf life determinations use the same testing protocols as the characterization testing which are based on ISO 4049.

Cytotoxicity testing according to 10993-05, irritation testing and sensitization testing according to ISO 10993-10 and acute systemic toxicity testing according to ISO 10993-11 were conducted and passed.

Predicate Device: Clip Flow K153493 from Voco Gmbh

Reference Devices: Renew MDP K231696 from Prevest Denpro

Substantial Equivalence:

The Sil-Flow has similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Sil-Flow from DSI

	Sil-Flow	Clip Flow from Voco Gmbh K153493	Renew MDP K231696 from Prevest Denpro
Product Code	EBF	EBF	KLE
Indications for Use	Sil-Flow is indicated for • Temporary inlay and onlay treatments of the cavity • Sealing of openings for implant screws • Relining material for temporary crowns and bridges • Block-out material for retentive areas in the dental arch, e.g. before taking impressions • Covering of the gingival margin • Fixing of resin matrix during filling placement • Temporary filling of cavities	Clip Flow is indicated for • Temporary inlay and onlay treatments of the cavity • Sealing of openings for implant screws • Relining material for temporary crowns and bridges • Block-out material for retentive areas in the dental arch, e.g. before taking impressions • Covering of the gingival margin • Fixing of resin matrix during filling placement • Temporary filling of cavities	Renew MDP is indicated for bonding of dual cure, light cure or self cure composite or compomer restorations to tooth structure, treatment of hypersensitive teeth, and intraoral repairs of fractured restorations.
Applicable Standards	ISO 4049	ISO 4049	

Mechanism of Action	Filling and sealing	Filling and sealing	bonding
Composition	-Bis-GMA -Urethane Dimethacrylate -Hydroxethylmethyl-acrylate -Silicon dioxide -Camphorquinone -Ethyl-4 Di methyl amino benzoate -Butylated hydroxy toluene (BHT)	-Urethane Dimethacrylate -Hydroxethylmethyl-acrylate -Silicon dioxide	• Bis-GMA • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Hydroxethylmethyl acrylate • Ethanol • Camphorquinone • Ethyl-4 Di methyl amino benzoate • Butylated hydroxy toluene (BHT) • 2-dimethyl amino ethyl Methyacrylate • DM water • 10-Methacryloxydecyl Dihydogen Phosphate
Surface Hardness	52 Shor D	90 Shore A	
Water Sorption ISO 4049 ≤ 40 µg/mm^3	<40 µg/mm^3	<40 µg/mm^3	
Water Solubility ISO 4049 ≤ 7.5 µg/mm^3	<7.5 µg/mm^3	<7.5 µg/mm^3	
Depth of Cure (mm)	3.1mm	11mm	
Shelf Life	3 years	3 years	

Conclusion: Sil-Flow is substantially equivalent to the predicate device. They have the same indications, similar testing, and very similar ingredients. Both the subject devices and the predicate device have physical parameters which meet the requirements of the relevant ISO standards. Shelf life testing is similar to the shelf life testing of predicate or reference device. Reference device is included to cover any ingredients not covered by the predicate device. Any differences in ingredients are minor and do not change the substantial equivalence.