May 31, 2024

Dreve Denatmid GmbH
℅ Nevine Erian
Regulatory Consultant
BQC Consulting, LLC
24341 Barbados Dr.
Dana Point, California 92629

Re: K241226
Trade/Device Name: Fixtemp® C&B 4:1
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: May 1, 2024
Received: May 2, 2024

Dear Nevine Erian:

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.

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

Submission Number *(if known)*

K241226

Device Name

Fixtemp® C&B 4:1

Indications for Use *(Describe)*

Fixtemp® C&B 4:1 is a resin-based material used to fabricate temporary crowns and bridges.

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.

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510(k) Summary
K241226

Submitter	**Dreve Dentamid GmbH** Max-Planck-Strasse 31 59423 Unna, Nordrhein-Westfalen, Germany Establishment Reg. No. 1000486347
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Official Correspondent	Ms. Nevine Erian Regulatory Consultant **BQC Consulting LLC** 24341 Barbados Dr. Dana Point, CA 92629 **Phone** (949) 370-7155 **Fax** (949) 240-8829 **E-mail** nevine@bqcconsulting.com
Date Prepared	May 1, 2024

- **Trade/Device Name** Fixtemp® C&B 4:1
- **Common Name** Temporary crown & bridge resin
- **Classification Name** Crown and Bridge, Temporary, Resin
- **Regulation Number** 21 CFR 872.3770
- **Product Code** EBG

Predicate Device

Fixtemp® C&B (Dreve Dentamid GmbH.) – K171729 – ***Primary Predicate***

Device Description

Fixtemp® C&B 4:1 is an automatically mixable self-curing composite, used for the direct and indirect fabrication of temporary crowns and bridges. Fixtemp C&B 4:1 is a Type 1 – polymer-based material, per ISO 10477:2020. It is available in the tooth colors A1, A2, A3, A3.5, B1 and Bleach X.

Statement of Intended Use

Fixtemp® C&B 4:1 is intended for the production of temporary crowns and bridges.

Statement of Indication for Use

Fixtemp® C&B 4:1 is a resin-based material used to fabricate temporary crowns and bridges.

Material Composition

Fixtemp® C&B 4:1 is a methacrylate-based resin.

Technological Characteristics

Fixtemp® C&B 4:1 is a self-curing resin.

Non-Clinical Performance Testing

Fixtemp® C&B 4:1 was tested and met the applicable requirements of the following FDA Recognized Consensus standard:

- ISO 10477:2020 – Dentistry – Polymer-based crown and veneering materials

Bench test results allowed us to conclude that Fixtemp® C&B 4:1 meets its intended use.

Biocompatibility

Fixtemp® C&B 4:1 meets the biocompatibility requirements of the following standards:

- ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 7405:2008 Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of Fixtemp® C&B 4:1.

Substantial Equivalence

The technical characteristics of Fixtemp® C&B 4:1 is substantially equivalent to the predicate device.

Material

Fixtemp® C&B 4:1 is a resin-based material as the predicate device.

Physical Properties

Fixtemp® C&B 4:1 has similar physical properties as the predicate device.

Technical Comparison of Fixtemp® C&B 4:1 to Predicate Device

Attribute	**Fixtemp® C&B 4:1**	**Fixtemp® C&B**
Indications		
Resin based material used to fabricate temporary crowns and bridges	Yes	Yes
Physical Property		
Type 1 material per ISO 10477	Yes	Yes
Initiator & Activator	Yes	Yes
In Double Cartridge	Yes	Yes
Uses a Mixing Cannula	Yes	Yes
Paste-like Liquid	Yes	Yes
Self-curing Resin	Yes	Yes
Shades	A1, A2, A3, A3.5, B1, Bleach X	A1, A2, A3, A3.5, B1, Bleach X
Material Attributes		
Chemical Characterization	Mixture of multifunctional (meth)acrylates, glass powder, aerosil, polyester, catalyst and pigments.	Mixture of multifunctional (meth)acrylates, glass powder, aerosil, polyester, catalyst and pigments.
Mixing Ratio	4:1 (Base:Catalyst)	10:1 (Base:Catalyst)
Material Type	Paste-like Liquid	Paste-like Liquid
Shelf Life	2 years	2 years

Attribute	**Fixtemp® C&B 4:1**	**Fixtemp® C&B**
Technical Attributes		
Method of manipulation	Impression or thermoforming blank	Impression or thermoforming blank
Polymerization (Curing Method)	Self-curing resin	Self-curing resin
Processing/Working Time	≥ 45 sec	≥ 45 sec
Curing Time in the mouth	≈ 2 - 3 min	≥ 2 - 3 min
Setting Time	≥ 6 min	≥ 6 min
Flexural Strength	> 60 MPa	> 60 MPa
Water Sorption	≤40 µg/mm^3	≤40 µg/mm^3
Duration	Short term < 30 days	Short term < 30 days
Sterile	No	No
Environment of Use	Dental Practice/Dental Laboratory	Dental Practice/Dental Laboratory

The differences in physical properties between Fixtemp® C&B 4:1 and the predicate device do not impact safety and effectiveness, as the finished clinical product meets the same performance requirements regardless of the material variation.

Conclusion

Information provided in this application demonstrates that Fixtemp® C&B 4:1 is substantially equivalent to the predicate device. Fixtemp® C&B 4:1 has the same indications for use, similar material composition, similar physical properties and technological characteristics as the predicate device.