4/10/2018

Dreve Dentamid GmbH
Reiner Altmann
Head of Quality Management & Regulatory Affairs
Max-Planck-Strasse 31
Unna, DE 59423 NRW

Re: K171729
Trade/Device Name: Fixtemp C&B
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary crown and bridge resin
Regulatory Class: Class II
Product Code: EBG
Dated: November 17, 2017
Received: November 20, 2017

Dear Reiner Altmann:

This letter corrects our substantially equivalent letter of December 13, 2017.

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171729

Device Name
Fixtemp® C&B

Indications for Use *(Describe)*
Fixtemp® C&B 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

Dreve Dentamid

- Submitter: Dreve Dentamid GmbH
  Max-Planck-Straße 31
  Unna, Nordrhein-Westfalen, 59423
  Germany

  Establishment Reg. No. 1000486347

- Contact: Dr. Reiner Altmann
  (Head of Quality Management and
  Regulatory Affairs)
  Phone: +49-2303-88070
  E-mail: reiner.altmann@dreve.de

- Official Correspondent: Mr. Michael Breer
  (Quality Management Representative)

- Date Prepared: December 12th, 2017

- Common Name: Temporary C&B resin
- Trade/Device Name: Fixtemp® C&B
- Model No.: D60391, D60392, D603925, D60393, D603935, D60394, D60395, D60396, D60399
- Classification Name: Crown and bridge, Temporary, Resin
- Device Classification: Class 2 per 21 CFR 872.3770
- Product Code: EBG

Predicate Device: K102917 FixTemp C&B™

Device Description

Fixtemp® C&B is a two-component automatically mixable composite on the basis of multifunctional (meth)acrylates provided in standard double cartridges. The material is dispensed and mixed by cartridge/mixing tip combination and it is used for the manufacturing of temporary crowns and bridges for use until the permanent restoration is fabricated. It can be also used for inlays, onlays and veneers and is available in tooth-colors A1, A2, A3, A3.5, B1, Bleach X and D2. This is a *prescription only* material. The labeling and working instructions are designed for health care professionals.

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The associated accessories include mixing tips as follows:

- Trade/Device Name: Mixing tips
- Product code: EID
- Classification name: Syringe, restorative and impression material
- Device classification: Class 1 as per 21 CFR 872.4565
- Listing No.: D244388

Indications for Use:

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

Substantial Equivalence

Information provided in this application shows that the product is substantially equivalent to the predicate device in indications for use, performance, materials and application. The main difference between these devices is the mixing ratio but the Fixtemp® C&B is substantial equivalent as shown in the substantial equivalence comparison. The difference in the mixing ratio does not alter the intended use of the device.

Technological Characteristics

Design

The Fixtemp® C&B of Dreve is similar in design to the predicate listed above. Same as the predicate the Fixtemp® C&B is intended to manufacture temporary crowns and bridges, as well as inlays, onlays and veneers. They use similar technological characteristics and principles. Both materials are two component materials being mixed to start the curing process.

Material

Same as the predicate material, the Dreve Fixtemp® C&B is based on multifunctional (meth)acrylates, glass powder, aerosil, polyester and catalyst. An assessment of the biocompatibility according to FDA Recognized Consensus Standard DIN EN ISO 7405 / ISO 10993-1 is included in this application. As a result of this assessment/testing we conclude that the device is substantial equivalent.

Some chemicals are part of Fixtemp® C&B (Dreve) but not available in the predicate`s composition, but also used in other devices of *product code EBG* for *crown and bridge, temporary, resin* like K122039, K033022, K042820 and K013674.

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Testing

The Fixtemp® C&B has benefited from design, development, testing and production procedures that are being certified according to ISO 13485; CAN/CSA ISO 13485 and European Medical Device Directive 93/42/EEC by a Notified Body.

Testing has confirmed that this device meets its product specification. A series of in-house tests have been conducted to verify the intended signals are accurate and can maintain performance over its useful life. The testing also demonstrated that the specification is substantial equivalent as the predicate and for details please refer to the substantial equivalence comparison.

Furthermore the material is:

- patient-contacting
- non-sterile

Summary non-clinical performance data

CHARACTERISTICS	Comments
Materials[1]	Mixture of multifunctional (meth)acrylates, glass powder, aerosil, polyester and catalyst. The used raw materials are state-of-the-art and are not known to have unacceptable risks or dangers when used as ingredients.
Chemical Description	Self-curing resin (radical polymerization)
Method of manipulation	Impression or thermoforming blank
Flow properties	Paste-like liquid
Working / Processing time	≥ 45 sec
Curing time in the mouth-flexible phase	≥ 2 – 3 min
Setting time	≥ 6 min
Hardness	1h: > 75 Shore D 24h: > 80 Shore D
Compressive strength	≥ 200 MPa according to DIN EN ISO 4049:2010.
Flexural strength	≥ 60 MPa according to DIN EN ISO 4049:2010.

[1] For a detailed formulation for Fixtemp® C&B of Dreve Dentamid please refer to table 1 Section B6.

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E-modulus	≥ 1500 according to DIN EN ISO 4049:2010
Water absorption	Pass according to DIN EN ISO 4049:2010.
Radiopacity	≥ 1.00 mm aluminium/mm material according to DIN EN ISO 4049:2010.
Safety – toxic	The cytotoxicity of cured Fixtemp® C&B was tested based on ISO 10993-5 by the independent laboratory Toxikon. The potential biological reactivity of a mammalian cell culture (mouse fibroblasts L929) in response to the test article Fixtemp® C&B was determined. There was no biological reactivity (grade 0) of the cells exposed to the test article. The test item Fixtemp® C&B (Lot# FE140814-27C - 601606x0) was considered to have no cytotoxic potential and to meet the requirements of ISO 10993-5. For details please refer to the test report "Toxikon Europe Final GLP Report: 17-01389-G1" in section B11.
Safety – carcinogenic	During the application uncured Fixtemp® C&B has direct contact with the patients' dentin and mucosal membrane. The biological risk during the application is negligible because of the short intraoral time < 3min. Different evaluations and assessments have been made for cured Fixtemp® C&B and they have shown that there is no evidence for causing cancer within the time period of use in the patients mouth for up to 29 days.
Safety – mutagenic	During the application uncured Fixtemp® C&B has direct contact with the patients' dentin and mucosal membrane. The biological risk during the application is negligible because of the short intraoral time < 3min. Different evaluations and assessments have been made for cured Fixtemp® C&B and they have shown that there is no evidence for mutagenic reactions within the time period of use in the patients mouth for up to 29 days.
Safety – irritating	During the application uncured Fixtemp® C&B has direct contact with the patients' dentin and mucosal membrane. The biological risk during the application is negligible because of the short intraoral time < 3min. Different evaluations and assessments have been made for cured Fixtemp® C&B and they have shown that there is no evidence for irritation within the time period of use in the patients mouth for up to 29 days.

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Safety – sensitizing	During the application uncured Fixtemp® C&B has direct contact with the patients' dentin and mucosal membrane. The biological risk during the application is negligible because of the short intraoral time < 3min. Different evaluations and assessments have been made for cured Fixtemp® C&B and they have shown that there is no evidence for sensitization within the time period of use in the patients mouth for up to 29 days.
Keeping (storage) quantities	The results of stability tests at 23 °C/37 °C justify to assume a shelf life of 2 years for Fixtemp® C&B.
Duration	Short term contact < 30 days
Type of contact	oral cavity as far as the pharynx
Conformance to consensus standard	EN ISO 13485:2012 ISO 7405:2008 ISO 10993-1:2009 ISO 14971:2007

Conclusion

There are no substantial differences between the Fixtemp® C&B defined in this 510(k) submission and other legally marketed devices in the United States. The device is substantially equivalent to predicate device FixTemp C&B™ listed by company Exacta Dental Direct. The materials function similar and have the same indications for use.

Same as the predicate the Fixtemp® C&B is state-of-the-art resin based material used to fabricate temporary crowns and bridges by intra-oral application and extra-oral final polymerization.

Dreve Dentamid GmbH

i.A. Dr. Reiner Altmann
(Head of Quality Management / Quality Control / Regulatory Affairs
& Safety Representative for Medical Devices)

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