May 29, 2019

DMG Chemisch-Pharmazeutische Fabrik GmbH
Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K183337

Trade/Device Name: LuxaCrown
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG, POW
Dated: April 26, 2019
Received: April 30, 2019

Dear Pamela Papineau:

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. 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 located 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.

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
status 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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,

Srinivas Nandkumar -S

for Malvina B Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

LuxaCrown is a self-curing composite for the fabrication of semi-permanent crowns and bridges. The material is mixed automatically.

Specifically:

Crown restorations:
• For restoration of the anatomical form in order to provide durable protection for the remaining tooth
• In order to restore chewing function
• For esthetic corrections

Bridge restorations:
• In order to restore chewing function
• For esthetic corrections

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Summary

K18337

Date Prepared
26 April 2019

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Subject Device Regulatory Information

Trade Name: LuxaCrown
Common Name: Long-term Temporary Crown and Bridge Resin
Product Code: EBG, POW
FDA Regulation: 21 CFR 872.3770
Device Classification: Class II
Legally Marketed Predicate and Reference Devices

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Device Description

LuxaCrown is a bis-acrylic resin-based self-curing composite for the fabrication of semi-permanent crowns and bridges. LuxaCrown is available in a range of shades to ensure an aesthetically-pleasing restoration. LuxaCrown is a non-sterile device intended for use by licensed dental professionals. Because LuxaCrown is intended for the fabrication of semi-permanent dental restorations, it may remain in the oral cavity for more than 30 days.

LuxaCrown is supplied in dual-barreled syringes for use with the DMG Automix self-mixing dispenser and Automix Tips, which were previously cleared in K101710 (DMG LuxaTemp Ultra), K013674 (DMG LuxaTemp) and K924830 (DMG LuxaTemp Automix).

Indications for Use

LuxaCrown is indicated for use for the fabrication of semi-permanent crowns and bridges. The LuxaCrown indications for use statement lists the following examples of specific uses:

- Crown restorations:
  - For restoration of the anatomical form in order to provide durable protection for the remaining tooth
  - In order to restore chewing function
  - For esthetic corrections
Bridge restorations:
- In order to restore chewing function
- For esthetic corrections

The indications for use statement for the predicate Zirkonzahn products cleared in K180562 (Temp Premium, Temp Premium Flexible, Multistratum Flexible and Therapon) are very similar:

The resin discs TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE and THERAPON are polymethylmethacrylate and polycarbonate discs indicated to manufacture temporary anterior and posterior crowns and bridges, with up to two adjacent pontics, that can be kept in the mouth for up to 12 months.

Differences between the LuxaCrown and the predicate device indications for use, and the justification for each of these differences, are as follows:

1. LuxaCrown is not supplied in the form of resin discs. The “Product Description” section of the LuxaCrown IFU states that LuxaCrown is an automatically mixed, self-curing composite; therefore, it is not necessary to identify the physical form of the product in the indications statement. Also, as demonstrated through testing based on ISO 10447, despite differences in raw materials and physical form, LuxaCrown and the predicate devices are equivalent in terms of physical properties supporting the devices’ ability to perform as intended. The 3M ESPE Protemp Plus reference device (K073296) is an example of a legally marketed product with a composition very similar to that of LuxaCrown, with very similar indications for use.

2. The LuxaCrown indications for use do not mention “anterior and posterior” crowns and bridges. This is a wording difference only; by not specifying “anterior and posterior” it is clear that LuxaCrown can be used for both anterior and posterior applications.

3. The predicate Zirkonzahn TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE and THERAPON indications specify a maximum of two adjacent pontics for restorations fabricated with the devices cleared in K180562. The equivalent information is contained in the LuxaCrown instructions for use, which include the following Contraindication: “Do not use this material for bridges with more than two adjacent pontics”.

4. The examples of LuxaCrown uses for crowns (“for restoration of the anatomical form in order to provide durable protection for the remaining tooth”, “in order to restore chewing function” and “for esthetic corrections”) and bridges (“in order to restore chewing function” and “for esthetic corrections”) are standard dental
5. LuxaCrown refers to the fabrication of “semi-permanent” crowns and bridges; the predicate Zirkonzahn indications specify “a maximum recommended usage time of 12 months”. The 3M ESPE ProTemp Plus reference device (K073296) indications refer to the fabrication of “long-lasting temporary” restorations. The terms “semi-permanent” and “long-lasting” have no specific definition in dentistry other than to signal an acceptable period of use beyond the interval ranging from several days to several weeks typically indicated by the descriptor “short-term”, or even by the word “temporary” alone. DMG has provided test data collected in a chewing simulator to demonstrate that crowns made from LuxaTemp survive cyclic loading for the equivalent of > 5 years. Therefore, this difference in terminology is supported by laboratory testing.

Discussion of Non-Clinical Tests

LuxaCrown was tested in accordance with ISO 10447:2004 to determine physical characteristics such as flexural strength, water sorption and water solubility. Internal DMG test methods were used to test other characteristics not addressed in ISO 10477 (working time, setting time, compressive strength). The results of these tests were compared to the DMG product specification for LuxaCrown, and to data for the primary predicate and reference devices. All samples met the requirements of internal product specifications and were within the limits specified in ISO 10477.

A biocompatibility assessment documented for LuxaCrown established that the product meets the requirements of ISO 10993-1:2009 and ISO 7404:2008 with respect to biocompatibility. The LuxaTemp biocompatibility assessment was supported by biocompatibility testing conducted in accordance with ISO 10993-3 (mutagenicity), ISO 10993-5 cytotoxicity) and ISO 10993-10 (sensitization/irritation). LuxaCrown was determined to meet all biocompatibility requirements for dental materials.

Testing was performed to support the 2-year shelf life of LuxaCrown using device samples that were aged in accordance with the guidelines described in ASTM F1980. Physical properties (working time, setting time, flexural strength, compressive strength, fracture toughness, polymerization shrinkage, smear layer and peak polymerization temperature) of the aged samples were measured to confirm that the device continues to meet specifications with no significant degradation in physical properties at the end of the labeled shelf life. This testing demonstrated that LuxaCrown remains stable over the 2-year product shelf life.
Conclusion

Based on a comparison of the device indications for use, technical specifications, biocompatibility and physical properties, LuxaCrown has been shown to be substantially equivalent to the predicate device.