September 11, 2019

Zest Anchors, LLC
Marysa Loustalot
Sr. Regulatory Affairs Specialist
2875 Loker Avenue East
Carlsbad, California 92010

Re: K191619
Trade/Device Name: TurboTemp EZ
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary crown and bridge resin
Regulatory Class: Class II
Product Code: EBG, POW
Dated: June 14, 2019
Received: June 18, 2019

Dear Marysa Loustalot:

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

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) for devices or postmarketing safety reporting (21 CFR 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 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 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 Adjodha
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191619

Device Name
TurboTemp EZ

Indications for Use *(Describe)*
TurboTemp EZ is a is a self-cure crown-and-bridge composite indicated for the fabrication of long- and short-term provisional restorations including veneers, inlays/onlays, crowns, partial crowns, bridges and long-span bridges. TurboTemp EZ is also indicated for incorporation of most mechanically anchored attachment components into the acrylic base of a denture, an overdenture, or a partial denture.

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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Section 5.0 510(k) Summary

I. SUBMITTER

Zest Anchors, LLC
2875 Loker Ave. East.
Carlsbad, CA 92010
Phone: (760) 743-7744
Contact: Marysa Loustalot ext. 596
Date Prepared: June 14, 2019

II. DEVICE INFORMATION

Device / Trade Name: TurboTemp EZ
Common Name: Temporary crown and bridge resin
Classification Name: Crown and Bridge, Temporary Resin
Regulatory Classification: 872.3770, Class II
Product Code: EBG, POW

III. PREDICATE DEVICE

Device / Trade Name: Luxatemp Ultra
510(k): K101710
Applicant: DMG USA, INC

REFERENCE DEVICE
Device / Trade Name: DMRC Bulk Fill (Bulk EZ)
510(k): K151088
Applicant: Danville Materials, LLC (Now Zest Anchors, LLC)

IV. DEVICE DESCRIPTION

TurboTemp EZ is a provisional resin based material intended to be used for the fabrication of crowns, bridges, inlays, onlays, and veneers. The composite material is provided in a dual-barrel cartridge that when combined in the mixing tip, it is dispensed as a self-curing restorative material.

V. INDICATIONS FOR USE

TurboTemp EZ is a is a self-cure crown-and-bridge composite indicated for the fabrication of long- and short-term provisional restorations including veneers, inlays/onlays, crowns, partial crowns, bridges and long-span bridges. TurboTemp EZ is also indicated for incorporation of most mechanically anchored attachment components into the acrylic base of a denture, an overdenture, or a partial denture.

VI. COMPARISON TO PREDICATE DEVICE

The subject device (TurboTemp EZ) has the same indications for use, the same curing features, uses the same type of resin and fillers, and has the same mode of operation as the legally marketed predicate device (Luxatemp Ultra).

Attribute	Subject Device	Predicate Device	SE
510(k) Number	TBD	K101710	✓
Name	TurboTemp EZ	Luxatemp Ultra	✓
Manufacturer	Zest Dental Solutions	DMG USA, Inc	✓
Indications for Use	TurboTemp EZ is a is a *self-cure crown-and-bridge composite* indicated for the fabrication of long- and short-term provisional restorations including veneers, inlays/onlays, crowns, partial crowns, bridges and long-span bridges. TurboTemp EZ is also indicated for *incorporation of most mechanically anchored attachment components into the acrylic base of a denture, an overdenture, or a partial denture.*	Luxatemp Ultra/Star is a *self-curing* or dual-curing *composite* for the fabrication of temporary crowns and bridges, inlays, onlays and veneers. Luxatemp Ultra/Star is intended for the fabrication of: • temporary crowns • bridges • inlays • onlays • long-term temporaries • temporary veneers Luxatemp Ultra/Star is also indicated for *incorporation of most mechanically anchored attachment components into the acrylic base of a denture, an overdenture or partial denture.*	✓
Product Code	EBG	EBG	✓
Classification	21 CFR 872.3770	21 CFR 872.3770	✓
RX/OTC	RX	RX	✓
Features	Self-curing	Self-curing & Dual-curing	✓
Mode of Operation	Dual-barrel cartridge	Dual-barrel cartridge	✓
Resin System	Dimethacrylate	Dimethacrylate	✓
Fillers	Silica-based glass fillers	Glass fillers	✓
Transverse Strength	94 MPa	100 MPa	✓
Water Sorption	17.111µg/mm³	20 u/mm³	✓
Components	2	2	✓

VII. PERFORMANCE TESTING

Performance testing of TurboTemp EZ has demonstrated compliance to ISO 10477 Dentistry - Polymer-Based Crown and Veneering Materials, ISO 4049 Dentistry - Polymer-Based Restorative Materials, and meets the suggested characteristics as described in FDA's *Guidance for Industry and FDA Staff, Dental Composite Resin Devices – Premarket Notification [510(k)]* issued on October 26, 2005. Therefore it can be concluded that the TurboTemp EZ is substantially equivalent to its predicate device, Luxatemp Ultra.

The primary chemical composition of TurboTemp EZ is equivalent to the reference device DMRC Bulk Fill (commercial name, Bulk EZ) cleared under K151088. The chemicals which are contained in both devices are equivalent in quantities and serve the identical function. A biological evaluation of TurboTemp EZ has been conducted and a review of the biological properties has concluded that the TurboTemp EZ is substantially equivalent to the legally marketed Bulk EZ and complies with ISO 7405, the FDA guidance for Dental Composite Resin Devices, and ISO 10993-1.

VIII. CONCLUSION

Performance testing to ISO 10477 and ISO 4049, along with the biological evaluation of the subject device, demonstrate that the TurboTemp EZ is substantially equivalent to the Luxatemp Ultra (K101710).