May 5, 2020

Enlighten Materials Co., Ltd
% Chiao-Min Chang
Regulatory Affairs
Voler Biotech Consulting Co., Ltd.
No. 3-1, Ln 58, Hejiang St., Zhongshan Dist.,
Taipei City, 10480 TAIWAN

Re: K191590
Trade/Device Name: AA temp temporary restoration 3D printing photoreactive resin
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: March 29, 2020
Received: April 3, 2020

Dear Chiao-Min Chang:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K191590

Device Name
AA temp temporary restoration 3D printing photoreactive resin

Indications for Use *(Describe)*
AA temp temporary restoration 3D printing photoreactive resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges and require digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.

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.

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510(k) SUMMARY

K191590

Contact Person

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Title: Chief Executive Officer

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Device Name and Classification

Product Name:	AA temp temporary restoration 3D printing photoreactive resin
Classification Name:	Temporary crown and bridge resin.
Common or Usual Name:	Dental Material
Classification Panel:	Dental Device
Regulation Number:	872.3770
Device Class:	Class II
Product Code:	EBG

Predicate Device

Product Name:	K102776 e-DENT TEMPORARY RESIN and EXTRA-ORAL CURING SYSTEM

Device Description

AA temp is a photosensitive resin intended for use to fabricate temporary crowns and bridges using CAD/CAM additive printing process. The AA temp polymer is a viscous solution of the following compounds: methacrylate-based resins, a photoinitiator that activates between 385nm to 405 nm light, and pigments. It comes in one size, one kilogram per bottle. It is compliant to the requirements defined in ISO 10477-2018 for Type 2 Class 2 materials. The material is used in a 3D printer, which prints the shape determined by a 3D stereolithographic drawing. After printing, the printed product is placed in a UV-light curing box for final polymerization. 3D printer is not included with the device.

Indications for Use

AA temp temporary restoration 3D printing photoreactive resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges and require digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.

Comparison to Technology

	K191590	K102776 Predicate Device	Differences
Item	AA temp temporary restoration 3D printing photoreactive resin	e-dent Temporary Resin and EXTRA-ORAL curing system	NA
Indication for use	AA temp temporary restoration 3D printing photoreactive resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges and require digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment.	The e-DENT TEMPORARY resin is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral light equipment.	Both devices are acrylates or methacrylates for the fabrication and repair of temporary crowns, bridges and CAD/CAM additive printing.

Device Description

	K191590	K102776 Predicate Device	Differences
Acrylic Resin	Light- Cure Resin	Light- Cure Resin	Identical
Chemical Characterization	Methacrylate-based resin	Methacrylate-based resin	Methacrylate-based resin
Polymerization (curing) Method	Visible light	Visible light	Identical
Inorganic Filler	0.49%	49.8 % by weight	Non-Identical
Product State	Pre-mix resin	Pre-mix resin	Identical
Fabrication of denture Base	CAD/CAM additive printing process	CAD/CAM additive printing process	Identical
Teeth Assemble	Bonding	Bonding	Identical

K102776 contains 49.8% of inorganic fillers and K191590 contains 0.49% of inorganic fillers. Higher filler content can enhance the wear resistance and adjust the optical properties of a resin. Higher filler content, however, may decrease the flowability of the resin and can possibly decrease the degree of conversion after light-curing. According to the physical properties table of the K191590 below, its lower filler content does not affect its flexural strength, water absorption and solubility. Moreover, K191590 also comply with all biocompatibility tests. Therefore, the difference in filler content will not raise concern of the safety and effectiveness.

Physical properties

	K191590	K102776 Predicate Device	Difference
Flexural Strength	>100MPa	>100MPa	Identical
Water Absorption	Complies with En ISO 10477	Complies with En ISO 10477	Identical
Solubility	Complies with En ISO 10477	Complies with En ISO 10477	Identical

Non-clinical performance testing

Chemical Test

- Test for Heavy Metals USEPA 3052 method.

Biocompatibility Testing

The biocompatibility evaluation for AA temp temporary restoration 3D printing photoreactive resin was conducted in accordance with the FDA Blue Book Memorandum #G95 and international Standard ISO 10993-1.

- Cytotoxicity
- Oral Mucosa Irritation Test
- Skin sensitization study (Maximization test)
- Acute Systemic Toxicity Study
- Genotoxicity – ONLY *Salmonella* Reverse Mutation Test was completed. Other three tests, including (1) an in vitro test with cytogenetic of chromosomal damage with mammalian cells (OECD 473), (2) an in vitro mouse lymphoma TK assay (OECD 476), modified for medical devices, including detection of small (slow growing) and large colonies , and (3) an in vitro mammalian cell micronucleus test for chromosomal damage and aneugenicity (OECD 487) will be completed by the end of July 2020.

Bench Testing

- ISO 10477. Dentistry–Polymer-based crown and bridge materials. 2018.

- Shelf life testing, AA TEMP has a shelf life of 2.5 years. The shelf testing has been conducted with the bench test from the ISO Standard 10477 and ISO 868.

Similarity and differences

Difference between the proposed device and predicate device is that this submission does not include Extra-ORAL CURING SYSTEM, only the Resin.

K102776 contains 49.8% of inorganic fillers and K191590 contains 0.49% of inorganic fillers. Higher filler content can enhance the wear resistance and adjust the optical properties of a resin. Higher filler content, however, may decrease the flowability of the resin and can possibly decrease the degree of conversion after light-curing. According to the physical properties table of the K191590 below, its lower filler content does not affect its flexural strength, water absorption and solubility. Moreover, K191590 also comply with all biocompatibility tests. Therefore, the difference in filler content will not raise concern of the safety and effectiveness.

Conclusion

Based on similarities in technology and indications for use, as well as results of non-clinical performance testing, AA temp temporary restoration 3D printing photoreactive resin is substantially equivalent to the predicate device.