August 18, 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: K191591
Trade/Device Name: BB Base 3D Printing Resin for Denture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: July 9, 2020
Received: July 20, 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

Indications for Use

510(k) Number

Device Name: BB Base 3D printing resin for denture base

Indications for Use:

Enlighten BB Base, developed by ENLIGHTEN MATERIALS Co., Ltd., is a light-cured resin indicated for the fabrication of full removable denture bases in dental laboratories. It is an alternative to traditional heat-cured, auto-cured or light-cured denture base resins. Enlighten BB Base should be used exclusively by dental professionals. Fabrication of denture bases with Enlighten BB Base requires a computer-aided and manufacturing (CAD/CAM) system including the following; optical impression system, design software (CAD software), stereolithographic additive printer, and post-cure unit.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)	X
Over-The-Counter Use (21 CFR 801 Subpart C)	

K191591

510(k) SUMMARY

BB Base 3D printing resin for denture base

1. Contact Person

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Title: Chief Financial Officer
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Office address: 8F., NO.138, SEC. 2, JINSHAN S. RD., DA-AN DIST., TAIPEI CITY 10642, TAIWAN (R.O.C.)
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2. Device Name and Classification

Date prepared:	2020.07.07
Product Name:	BB Base 3D printing resin for denture base
Classification Name:	Denture relining, repairing, or rebasing resin.
Common or Usual Name:	Dental Material
Classification Panel:	21 CFR 872.3760
Regulation Number:	872.3760
Device Class:	Class 2
Product Code:	EBI

3. Predicate Device(s)

Dentca Denture Base II
K162044

4. Device Description

BB Base is a photosensitive resin intended to fabricate removable dentures in a CAD/CAM additive printing process. The BB Base 3D printing resin for denture base 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 a Type 4 (light-activated) acrylic resin as classified ISO20795-1. 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.

5. Intended Use / Indications for Use

BB Base 3D printing resin for denture base, developed by ENLIGHTEN MATERIALS Co., Ltd., is a light-cured resin indicated for the fabrication of full removable denture bases in dental laboratories. It is an alternative to traditional heat-cured, light-cured or light-cured denture base resins. BB Base 3D printing resin for denture base should be used exclusively by dental professionals. Fabrication of denture bases with BB Base 3D printing resin for denture base requires a computer-aided and manufacturing (CAD/CAM) system including the following; optical impression system, design software (CAD software), stereolithographic additive printer, and post-cure unit.

Scanner and CAD software:

	Brand	Model
Scanner	Carestream	3600
Design software	Exocad	Exocad

Printing system：385~405nm 3D printers

Printer Brand	Model	Software
Miicraft	Ultra	MiiUtility

Post-Curing: 385~405nm UV box

Post-cure unit brand	Type
Formlabs	Form Cure

6. Comparison of technology

	Subject Device	Predicate Device
510(k) No.	K191591	Dentca Denture Base II (K162044)
Item	BB Base 3D printing resin for denture base	e-dent Temporary Resin and Extra-Oral
Classification	2	2
Product Code	EBI	EBI
Intended Use	Fabrication and repair of removable dentures	Fabrication and repair of removable dentures
Target population	Edentulus patients	Edentulus patients
Standard and Approvals	ISO20795-1 type 4 (light-cure denture base material)	ISO20795-1 type 4 (light-cure denture base material)

Device Description

	K191591 Subject Device	K162044 Predicate Device	Differences
Acrylic Resin	Light- Cure Resin	Light- Cure Resin	Identical
Chemical Characterization	Methacrylate-based resin	Methacrylate-based resin	Identical
Polymerization (curing) Method	Visible light	Visible light	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

Physical Properties

	K191591 Subject Device	K162044 Predicate Device	Comparison
Flexural Strength	>85.2 MPa	>65 MPa	Met the criteria of ISO 20975-1
Flexural modulus	>2049 MPa	>2000 MPa	Met the criteria of ISO 20975-1
Viscosity	~1180 cps	1000<x<2000	Met the criteria of ISO 20975-1

The physical properties of BB base are complied with ISO 20975-1, and these differences do not raise concerns of safety and effectiveness for this submission.

7. Performance Data

- Non-clinical performance testing

BB base has been tested for mechanical properties as part of the product specification. The most applicable standard for mechanical characteristics determination of denture base polymers and copolymers is the ISO 20975-1 Dentistry - Base polymers - Part 1: Denture base polymers.

BB base is considered a surface device, in contact with the mucosal membrane, for > 30 days. The ISO 10993-1 standard was followed, and the following biological safety aspects have been addressed:

- Cytotoxicity – ISO10993-5
- Sensitization – ISO10993-10
- Irritation or intracutaneous reactivity – ISO10993-10
- Acute systemic toxicity – ISO10993-11
- Genotoxicity – ISO 10993-3

We also conducted a risk assessment following ISO 14971 to conform the biocompatibility.

BB base has been tested for conformity with the industry standard ISO 20795-1. BB base is compliant to the requirements defined in ISO 20975-1 for Type 4 materials.

The following bench tests are conducted on BB base using all the compatible CAD/CAM systems, including the post-curing process:

- Flexural strength
- Flexural modulus
- Residual monomer
- Water sorption
- Water solubility

- Clinical Performance Testing

We did not conduct clinical performance testing for this submission device.

8. Conclusions:

Based on similar technology and Indications for Use as well as results of performance testing, we believe that BB Base 3D printing resin for denture base is substantially equivalent to the predicate, Dentca Denture Base II.