



ENLIGHTEN MATERIALS



AA Temp
Temp Crown
and Bridge

Class II



BB Base
denture base

Class II



CC Tray
custom tray

Class I



DD Guide
dental surgical guide

Class I



Dental model
Grey
Brown
Water washable





ENLIGHTEN MATERIALS

Registration

Product name	Classification	US FDA	CE	Taiwan FDA	Brazil ANVISA
AA Temp	Class II	OK	in preparation	OK	OK
BB base	Class II	OK	in preparation	OK	OK
CC Tray	Class I	OK	in preparation	OK	OK
DD guide	Class I	OK	in preparation	OK	OK
Dental Model	N/A				



ENLIGHTEN MATERIALS



AA Temp

Temp Crown and Bridge

Class II



BB Base

for denture base

Class II



CC Tray

for custom tray

Class I



DD Guide

for dental surgical guide

Class I

510(k) Premarket Notification

FDA Home Medical Devices Databases



510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
 CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search		Back To Search Results
Device Classification Name	Crown And Bridge, Temporary, Resin	
510(K) Number	K191590	
Device Name	AA Temp Temporary Restoration 3D Printing Photoreactive Resin	
Applicant	Enlighten Materials Co., Ltd 8F., NO.138, Sec.2, Jinshan S. Rd., Da-An Dist Taipei, TW 10642	
Applicant Contact	Jiun Ming Su	
Correspondent	Voler Biotech Consulting Co., Ltd. No. 3-1, Ln 58, Hejiang St., Zhongshan Dist., Taipei City, TW 10480	
Correspondent Contact	Chih-Hao Kao	
Regulation Number	872.3770	
Classification Product Code	EBG	
Date Received	06/14/2019	
Decision Date	05/05/2020	
Decision	Substantially Equivalent (SESE)	
Regulation Medical Specialty	Dental	
510k Review Panel	Dental	
Summary	Summary	
Type	Traditional	
Reviewed By Third Party	No	
Combination Product	No	



AA Temp Temp Crown and Bridge

Class II

FDA 510 (k): K191590
 Taiwan FDA: Class II
 Brazil FDA: Class II

Property	ISO standard	Requirement	Results*
Flexural strength	ISO10477	≥50 MPa	82.35 MPa
Water sorption	ISO10477	≤40 µg/mm ³	<25 µg/mm ³
Water solubility	ISO10477	≤7.5 µg/mm ³	<1.5 µg/mm ³
Surface Hardness	ISO187	≥80 Shore D	84.65
Viscosity	N/A	N/A	~498 cps
Biocompatibility	ISO10993	Non-cytotoxic	Comply

Color and curing options:

- BL (White)
- A1 (Light Yellow)
- A2 (Yellow)
- A3 (Orange)
- R2 (Red)
- DLP (Digital Light Processing)
- SLA (Stereolithography)
- LCD (Liquid Crystal Display)
- 385 nm (Curing wavelength)
- 405 nm (Curing wavelength)
- 1kg (Weight)



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

Property	ISO standard	Requirement	Results
Flexural strength	ISO20795-1	≥65 MPa	>85.2 MPa
Flexural modulus	ISO20795-1	≥2000 MPa	>2049 MPa
Water sorption	ISO20795-1	≤32 µg/mm ³	26.2 µg/mm ³
Water solubility	ISO20795-1	≤1.6 µg/mm ³	0.89 µg/mm ³
Residual MMA monomer	ISO20795-1	≤2.2 %(w/w)	0%
Surface Hardness	ISO187	≥80 Shore D	87.25
Viscosity	N/A	N/A	~1180 cps
Biocompatibility	ISO10993	Non-cytotoxic	Comply



BB Base for denture base

Class II

FDA 510 (k) : K191591
 Taiwan FDA: Class II
 Brazil FDA: Class II



Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for **Owner Operator Number :**
10079678

Establishment Name	Registration Number	Current Registration Yr
ENLIGHTEN MATERIALS CO., LTD. TAIWAN	No number listed	2021
<ul style="list-style-type: none"> Material, Impression Tray, Resin 		Specification Developer
<ul style="list-style-type: none"> Resin, Denture, Relining, Repairing, Rebasing 		Specification Developer
<ul style="list-style-type: none"> Crown And Bridge, Temporary, Resin 		Specification Developer
<ul style="list-style-type: none"> Accessories, Implant, Dental, Endosseous 		Specification Developer

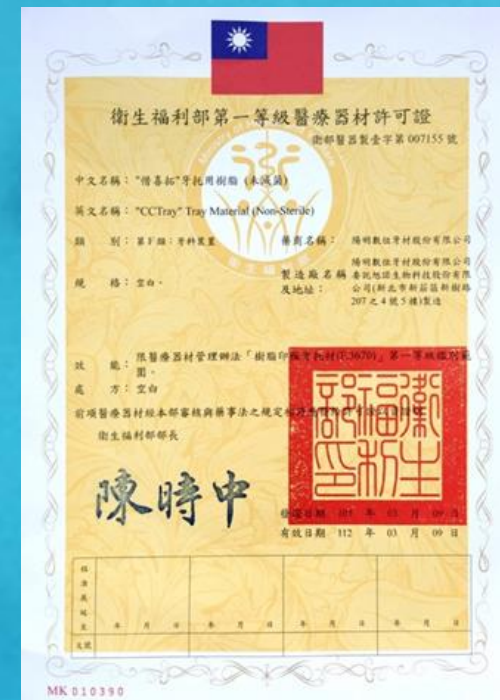
CC Tray

Class I

US FDA: Class I
Taiwan FDA: Class I
Brazil FDA: Class I

Property	Results
Flexural strength	95 MPa
Flexural modulus	2397 MPa
Surface Hardness	~78
Viscosity	~740 cps
Biocompatibility	Comply

DLP SLA LCD
 385 nm 405 nm
 1kg



Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for Owner Operator Number : 10079678

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<ul style="list-style-type: none"> Crown And Bridge, Temporary, Resin 		Specification Developer
<ul style="list-style-type: none"> Accessories, Implant, Dental, Endosseous 		Specification Developer

DD Guide

Class I

US FDA: Class I
Taiwan FDA: Class I
Brazil FDA: Class I

Property	Results
Flexural strength	90 MPa
Flexural modulus	1907 MPa
Water sorption	TBD
Water solubility	TBD
Surface Hardness	≥80 Shore D
Viscosity	720 cps
Biocompatibility	Comply



DLP SLA LCD

385 nm 405 nm

1kg



Dental Model

Brown

Property	Our results
Flexural strength	92 MPa
Flexural modulus	1875 MPa
Surface Hardness	86



DLP

SLA

LCD

385
nm

405
nm

1kg



Dental Model

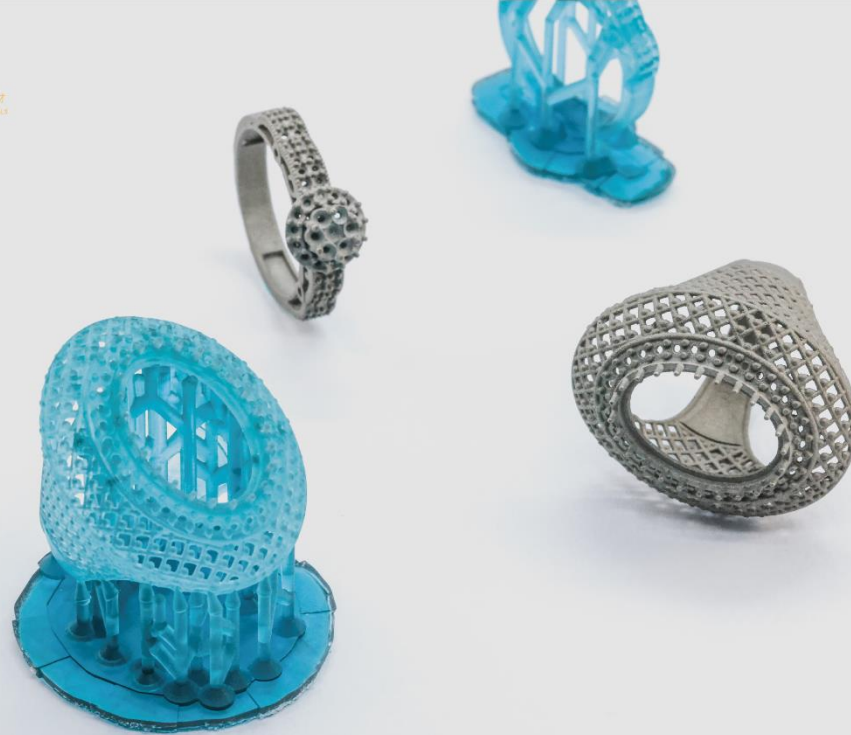
WW model

Brown

Water washable resin



Property	WW model
Flexural strength	65.7 MPa
Flexural modulus	1542 MPa
Elongation at break	15.26%
Surface Hardness	Shore 75.3D
Viscosity	75 – 85



KK CAST

KK Cast is a monomer-based acrylic resin for manufacturing 3D-printed castable parts with high flexural strength, hardness, low shrinkage, and low residue after casting.

KK Cast can be used for casting all types of dental metals, which will burn without residue at a minimum temperature of 700 °C over 45 minutes.

Property	Requirement	Result	ISO standard
Flexural strength	≥ 60 Mpa	≥ 70 Mpa	ISO 178
Flexural modulus	≥ 1500 Mpa	≥ 2100 Mpa	ISO 178
Hardness shore D	≥ 80 shore D	≥ 83 shore D	ISO 7619-1



THANK YOU



陽明數位牙材

ENLIGHTEN MATERIALS

Dental resins

for 3D printing

聯絡人: 蘇俊鳴 Jimmy

Email: jimmy.su.js@gmail.com