



ENLIGHTEN MATERIALS

產品介紹



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
Clear or LCD

Class I



WW Dental model
Brown
Water washable
Best seller
Not medical device



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



Medical Device Certification

Product name	Classification	US FDA	CE MDR	Taiwan FDA	Brazil ANVISA
AA Temp	Class II	✓	in preparation	✓	✓
BB base	Class II	✓	in preparation	✓	✓
CC Tray	Class I	✓	in preparation	✓	✓
DD guide	Class I	✓	in preparation	✓	✓
WW Dental Model	Not requiring				

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FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

510(k) Premarket Notification

FDA Home Medical Devices Databases

CDRH SuperSearch

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

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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 A1~A3

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

BL A1 A2 A3 R2

DLP SLA LCD

385 nm 405 nm

1kg





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

R2
R1
A2

DLP
SLA
LCD

385 nm
405 nm

1kg

BB Base for denture base R1 or R2

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

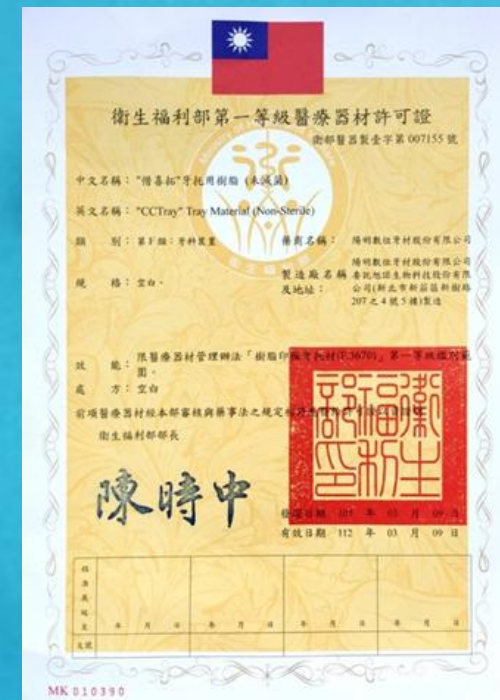
LCD

385 nm

405 nm

1kg





Establishment Registration & Device Listing

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<ul style="list-style-type: none"> Accessories, Implant, Dental, Endosseous 		Specification Developer

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




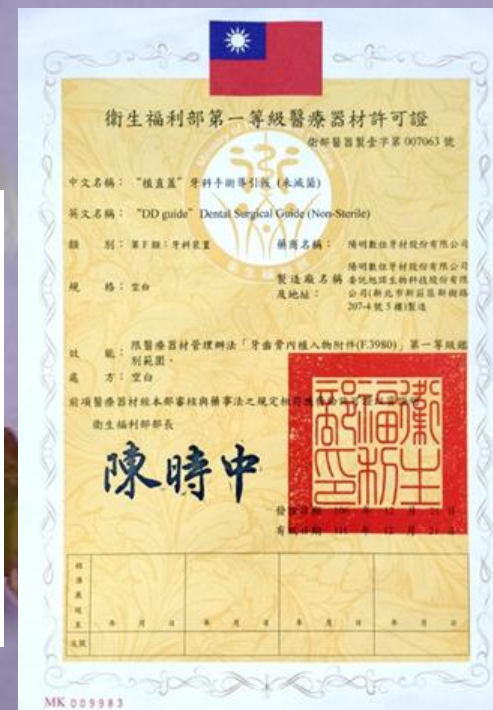
Property	Results
Flexural strength	90 MPa
Flexural modulus	1907 MPa
Water sorption	TBD
Water solubility	TBD
Surface Hardness	≥80 Shore D
Viscosity	720 cps
Biocompatibility	Comply

DLP
SLA
LCD

385 nm
405 nm

1kg





Dental Model

WW model

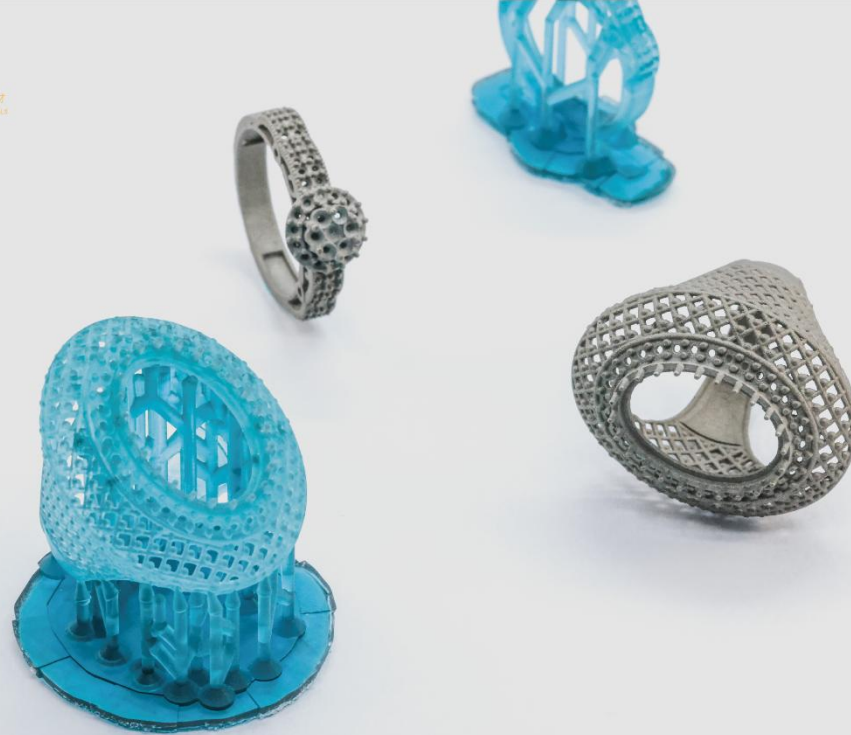
Brown

Water washable resin



Best seller product

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

Contact information:

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