

K191591 BB Base 3D printing resin for denture baseAug 18, 2020
431 days to decisionK191591 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k191591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jun 14, 2019
Decision date	Aug 18, 2020
Days to decision	431 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enlighten Materials Co., Ltd.
Location	Taipei, TW
Contact	Jiun Ming Su
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Voler Biotech Consulting CO., Ltd.
Contact	Chih-Hao Kao

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026