

**K191590 AA temp temporary restoration 3D printing  
photoreactive resin**May 5, 2020  
326 days to decisionK191590 · Product code: **EBG** · Dental  
Source: <https://www.510kdatabase.net/k191590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Jun 14, 2019
Decision date	May 5, 2020
Days to decision	326 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Voler Biotech Consulting CO., Ltd.</b>
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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191590/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026