

**K230455 Enamel Coating Resin**Jul 25, 2023  
154 days to decisionK230455 · Product code: **EBC** · Dental  
Source: <https://www.510kdatabase.net/k230455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Feb 21, 2023
Decision date	Jul 25, 2023
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rizhao Huge Biomaterials Company, Ltd.</b>
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	13 submissions · 13 cleared · 2020-2025

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