

**K254091 GLOSSY COAT (15ML)**Apr 6, 2026  
108 days to decisionK254091 · Product code: **EBD** · Dental  
Source: <https://www.510kdatabase.net/k254091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coating, Filling Material, Resin (EBD)
Date received	Dec 19, 2025
Decision date	Apr 6, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>YAMAHACHI DENTAL MFG., Co.</b>
Location	Gamagori, JP
Contact	Toyama Masashi
510(k) history	3 submissions · 3 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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