

**K250015 Ormco™ EtchFree Bonding System, Ormco™ EtchFree Bonding Primer, Ormco™ EtchFree Adhesive**

Jan 3, 2025  
1 days to decision

K250015 · Product code: **DYH** · Dental  
Source: <https://www.510kdatabase.net/k250015/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Jan 2, 2025
Decision date	Jan 3, 2025
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ormco Corporation</b>
Location	Orange, CA, US
Contact	Tara Bonny
510(k) history	6 submissions · 6 cleared · 2017-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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