

**K261840 BracePaste Prime Plus**Jun 3, 2026  
1 days to decisionK261840 · Product code: **DYH** · Dental  
Source: <https://www.510kdatabase.net/k261840/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Jun 2, 2026
Decision date	Jun 3, 2026
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>American Orthodontics</b>
Location	Sheboygan, WI, US
Contact	Laura Richmond
510(k) history	45 submissions · 45 cleared · 1989-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	DAVE YUNGVIRT

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261840/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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