

**K090355 OPAL SEAL**Apr 29, 2009  
77 days to decisionK090355 · Product code: **DYH** · Dental  
Source: <https://www.510kdatabase.net/k090355/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Feb 11, 2009
Decision date	Apr 29, 2009
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ultradent Products, Inc.</b>
Location	Salt Lake City, UT, US
Contact	DIANE ROGERS
Website	<a href="https://www.ultradent.com">https://www.ultradent.com</a>
510(k) history	103 submissions · 103 cleared · 1992-2026

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090355/> Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026