

K111696 OPAL BAND CEMENTSep 7, 2011
82 days to decisionK111696 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k111696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Jun 17, 2011
Decision date	Sep 7, 2011
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111696/> 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 18, 2026