

**K031915 PULPDENT ETCH-RITE ROYALE**Aug 5, 2003  
46 days to decisionK031915 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k031915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jun 20, 2003
Decision date	Aug 5, 2003
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pulpdent Corporation</b>
Location	Watertown, MA, US
Contact	KENNETH J BERK
510(k) history	32 submissions · 32 cleared · 2002-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031915/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 1, 2026