

**K041680 ORAJEL ADVANCED TOOTH DESENSITIZER**Nov 10, 2004  
142 days to decisionK041680 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k041680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jun 21, 2004
Decision date	Nov 10, 2004
Days to decision	142 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Del Pharmaceuticals, Inc.</b>
Location	Uniondale, NY, US
Contact	MARLENE TIETJEN
510(k) history	1 submissions · 1 cleared · 2004-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041680/> 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