

**K152322 Resolve 2.0**Dec 16, 2015  
121 days to decisionK152322 · Product code: **PME** · Dental  
Source: <https://www.510kdatabase.net/k152322/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Cleaning Solution (PME)
Date received	Aug 17, 2015
Decision date	Dec 16, 2015
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Denali Corporation</b>
Location	Hanover, MA, US
Contact	Jan G Stannard
510(k) history	9 submissions · 9 cleared · 2007-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152322/> 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 June 3, 2026