

**K102053 BUTLER CALCI-FLOR PROPHYLAXIS PASTE**Feb 3, 2011  
196 days to decisionK102053 · Product code: **EJR** · Dental  
Source: <https://www.510kdatabase.net/k102053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Polishing, Abrasive, Oral Cavity (EJR)
Date received	Jul 22, 2010
Decision date	Feb 3, 2011
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sunstar Americas, Inc.</b>
Location	Lake Bluff, IL, US
Contact	CARL JENKINS
510(k) history	3 submissions · 3 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102053/> 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 May 30, 2026