

**K171167 Prodigio Stain Powder**Dec 13, 2017  
236 days to decisionK171167 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k171167/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Apr 21, 2017
Decision date	Dec 13, 2017
Days to decision	236 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Operart, LLC</b>
Location	Santa Monica, CA, US
Contact	Domenico Cascione
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171167/> 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 31, 2026