

**K062400 IMPRESSIX, COLORCHANGE ALGINATE**Nov 16, 2006  
92 days to decisionK062400 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k062400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Aug 16, 2006
Decision date	Nov 16, 2006
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cavex Holland BV</b>
Location	Rw Haarlem (Holland), NL
Contact	RICHARD WOORTMAN
510(k) history	26 submissions · 26 cleared · 1998-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062400/> 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