

**K081084 COLORISE RIGID**May 14, 2008  
28 days to decisionK081084 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k081084/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Impression (ELW)
Date received	Apr 16, 2008
Decision date	May 14, 2008
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Zhermack S.P.A.</b>
Location	Bend, OR, US
Contact	GERALD W SHIPPS
510(k) history	19 submissions · 19 cleared · 1996-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081084/> 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 23, 2026