

**K043118 HYDROGUM SOFT**Jan 24, 2005  
75 days to decisionK043118 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k043118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Nov 10, 2004
Decision date	Jan 24, 2005
Days to decision	75 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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