

**K972027 ELITE H-D HYDROPHILIC VINYL POLYSILOXANE  
IMPRESSION MATERIALS (LIGHT BODY/NORMAL,LIGHT  
BODY/FAST SETTING,REGULAR BODY,)**Jul 16, 1997  
44 days to decisionK972027 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k972027/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 2, 1997
Decision date	Jul 16, 1997
Days to decision	44 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	EVAN DICK
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/k972027/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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