

K011130 PREMIUMJul 5, 2001
83 days to decisionK011130 · Product code: **ELM** · Dental
Source: <https://www.510kdatabase.net/k011130/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Denture, Plastic, Teeth (ELM)
Date received	Apr 13, 2001
Decision date	Jul 5, 2001
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	RAPHAEL JUDKINS
510(k) history	145 submissions · 145 cleared · 1988-2009

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