

**K033628 ARTIC**Jan 16, 2004  
58 days to decisionK033628 · Product code: **ELM** · Dental  
Source: <https://www.510kdatabase.net/k033628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Denture, Plastic, Teeth (ELM)
Date received	Nov 19, 2003
Decision date	Jan 16, 2004
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heraeus Kulzer, Inc.</b>
Location	Elkhart, IN, US
Contact	CHERYL V ZIMMERMAN
510(k) history	145 submissions · 145 cleared · 1988-2009

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