

**K042878 FLEXITIME XTREME**Dec 17, 2004  
60 days to decisionK042878 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k042878/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Oct 18, 2004
Decision date	Dec 17, 2004
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

**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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042878/> 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 May 20, 2026