

**K011036 RD-3008**May 10, 2001  
35 days to decisionK011036 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k011036/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Apr 5, 2001
Decision date	May 10, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Heraeus Kulzer, Inc.</b>
Location	Elkhart, IN, US
Contact	RAPHAEL JUDKINS
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/k011036/> 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