

**K980661 CERA E DENTAL ALLOY**May 1, 1998  
70 days to decisionK980661 · Product code: **EJS** · DentalSource: <https://www.510kdatabase.net/k980661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Other Noble Metal (EJS)
Date received	Feb 20, 1998
Decision date	May 1, 1998
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>European Dental Imports, Inc.</b>
Location	Durham, NH, US
Contact	GISELA N EVERNGAM
510(k) history	7 submissions · 7 cleared · 1998-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980661/> 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 July 2, 2026