

**K895064 MONOGRAM II**Dec 18, 1989  
132 days to decisionK895064 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k895064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Aug 8, 1989
Decision date	Dec 18, 1989
Days to decision	132 days
Third-party review	No

**APPLICANT**

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Company	<b>Leach and Dillon Co., Inc.</b>
Location	Mansfield, MA, US
Contact	CHERI KRATZ
510(k) history	31 submissions · 31 cleared · 1989-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895064/>; 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 4, 2026