

**K943968 TUNNELER**Mar 1, 1995  
198 days to decisionK943968 · Product code: **MDM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k943968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, Surgical, General Use (MDM)
Date received	Aug 15, 1994
Decision date	Mar 1, 1995
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Denver Biomedicals, Inc.</b>
Location	Englewood, CO, US
Contact	LYNNE LEONARD
510(k) history	10 submissions · 10 cleared · 1981-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943968/> 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 25, 2026