

**K981438 DORNIER MEDILAS E**Jul 20, 1998  
90 days to decisionK981438 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k981438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 21, 1998
Decision date	Jul 20, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dornier Surgical Products, Inc.</b>
Location	Phoenix, AZ, US
Contact	CAROL WERENCKE
510(k) history	9 submissions · 9 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981438/> 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 3, 2026