

**K130344 DORNIER MEDILAS UROPULSE**Mar 21, 2013  
38 days to decisionK130344 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k130344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 11, 2013
Decision date	Mar 21, 2013
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dornier Medtech America, Inc.</b>
Location	Marietta, GA, US
Contact	JOHN HOFFER
510(k) history	40 submissions · 40 cleared · 1990-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130344/> 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 June 9, 2026