

**K050218 WAVELIGHT SINON**Feb 15, 2005  
15 days to decisionK050218 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k050218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 31, 2005
Decision date	Feb 15, 2005
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wavelight Laser Technologie AG</b>
Location	North Reading, MA, US
Contact	MANFRED DRAX
510(k) history	8 submissions · 8 cleared · 2004-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050218/> 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 1, 2026