

**K011021 LASER 20**Oct 9, 2001  
188 days to decisionK011021 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k011021/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 4, 2001
Decision date	Oct 9, 2001
Days to decision	188 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ya-Man, Ltd.</b>
Location	Leesburg, FL, US
Contact	ROBERT T HANDREN
510(k) history	6 submissions · 6 cleared · 2001-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011021/> 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