

**K033933 POWERLITE 600 EX SYSTEM**Mar 16, 2004  
88 days to decisionK033933 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k033933/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 19, 2003
Decision date	Mar 16, 2004
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Preswede AB</b>
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	2 submissions · 2 cleared · 2003-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033933/> 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