

**K030883 OMNILUX BLUE**Jun 18, 2003  
90 days to decisionK030883 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k030883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 20, 2003
Decision date	Jun 18, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Photo Therapeutics Limited</b>
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	5 submissions · 5 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030883/> 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 29, 2026