

**K083748 IPULSE, MODEL: I150**Feb 2, 2009  
47 days to decisionK083748 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083748/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 17, 2008
Decision date	Feb 2, 2009
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cyden Limited</b>
Location	Swansea, Wales, GB
Contact	MICHAEL KIERNAN
510(k) history	21 submissions · 21 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083748/> 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 27, 2026