

**K163449 HyPHo Laser System**Jun 23, 2017  
197 days to decisionK163449 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k163449/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 8, 2016
Decision date	Jun 23, 2017
Days to decision	197 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hyper Photonics Srl</b>
Location	Vimercate Mb, IT
Contact	Isabella Carrer
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163449/> 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 1, 2026