

**K162454 PicoWay Laser System**Feb 1, 2017  
153 days to decisionK162454 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k162454/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 1, 2016
Decision date	Feb 1, 2017
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syneron Candela Corporation</b>
Location	Wayland, MA, US
Contact	Ruthie Amir
510(k) history	5 submissions · 5 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162454/> 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