

**K181523 Syneron CO2RE System**Jul 11, 2018  
30 days to decisionK181523 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 11, 2018
Decision date	Jul 11, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syneron-Candela Corp</b>
Location	Wayland, MA, US
Contact	Sharon Timberlake
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181523/> 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 30, 2026