

**K131649 ME**Dec 11, 2013  
189 days to decisionK131649 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k131649/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jun 5, 2013
Decision date	Dec 11, 2013
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syneron Beauty , Ltd.</b>
Location	Philedelphia, PA, US
Contact	JANICE M HOGAN
510(k) history	2 submissions · 2 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131649/> 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 7, 2026