

**K161952 UltraShape System**Nov 7, 2016  
115 days to decisionK161952 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161952/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Jul 15, 2016
Decision date	Nov 7, 2016
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syneron Medical, Ltd.</b>
Location	Yokneam Elite, IL
Contact	Ruthie Amir
510(k) history	35 submissions · 35 cleared · 2002-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161952/> 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