

K162163 UltraShape SystemNov 17, 2016
107 days to decisionK162163 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Aug 2, 2016
Decision date	Nov 17, 2016
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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