

**K132028 ULTHERA SYSTEM**Dec 11, 2013  
163 days to decisionK132028 · Product code: **OHV** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k132028/>**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 1, 2013
Decision date	Dec 11, 2013
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ulthera, Inc.</b>
Location	Mesa, AZ, US
Contact	SUZON LOMMEL
510(k) history	13 submissions · 12 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132028/> 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 27, 2026