

**K122528 ULTHERA SYSTEM**Aug 28, 2012  
8 days to decisionK122528 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k122528/>**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	Aug 20, 2012
Decision date	Aug 28, 2012
Days to decision	8 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/k122528/> 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