

K243035 Ulthera® SystemFeb 24, 2025
150 days to decisionK243035 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Sep 27, 2024
Decision date	Feb 24, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ulthera, Inc.
Location	Mesa, AZ, US
Contact	Scott Jewett
510(k) history	13 submissions · 12 cleared · 2009-2025

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