

K260618 Ulthera® SystemMay 21, 2026
85 days to decisionK260618 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Feb 25, 2026
Decision date	May 21, 2026
Days to decision	85 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	14 submissions · 13 cleared · 2009-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260618/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026