FDA 510(k) Premarket Notification

K260618 Ulthera® System

CLEARED

May 21, 2026
85 days to decision

K260618 · Product code: **OHV** · General & Plastic Surgery
Source: 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