

K250418 Ulthera System (UC-1 Control Unit PRIME Model 2.1)May 13, 2025
89 days to decisionK250418 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250418/>**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 | Feb 13, 2025 |
| Decision date | May 13, 2025 |
| Days to decision | 89 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

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