

K233996 Ulthera System (UC-1 Control Unit PRIME)Feb 22, 2024
66 days to decisionK233996 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233996/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Dec 18, 2023
Decision date	Feb 22, 2024
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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