FDA 510(k) Premarket Notification

K122528 ULTHERA SYSTEM

CLEARED

Aug 28, 2012
8 days to decision

K122528 · Product code: **OHV** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k122528/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Aug 20, 2012
Decision date	Aug 28, 2012
Days to decision	8 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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