FDA 510(k) Premarket Notification

# K132028 ULTHERA SYSTEM

**CLEARED**

Dec 11, 2013
163 days to decision

K132028 · Product code: **OHV** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k132028/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV) |
| Date received | Jul 1, 2013 |
| Decision date | Dec 11, 2013 |
| Days to decision | 163 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 |