FDA 510(k) Premarket Notification

K180623 Ulthera System

CLEARED

May 4, 2018
56 days to decision

K180623 · Product code: **OHV** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Mar 9, 2018
Decision date	May 4, 2018
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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