FDA 510(k) Premarket Notification

K161952 UltraShape System

CLEARED

Nov 7, 2016
115 days to decision

K161952 · Product code: **OHV** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k161952/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Jul 15, 2016
Decision date	Nov 7, 2016
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Syneron Medical, Ltd.**
Location	Yokneam Elite, IL
Contact	Ruthie Amir
510(k) history	35 submissions · 35 cleared · 2002-2017