

K231537 SofWave System

Aug 28, 2023
90 days to decision

K231537 · Product code: **OHV** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231537/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	May 30, 2023
Decision date	Aug 28, 2023
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sofwave Medical, Ltd.
Location	Yokneam, IL
Contact	Ruthie Amir, MD
510(k) history	12 submissions · 12 cleared · 2019-2025

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Device record: <https://www.510kdatabase.net/k231537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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