

K230019 SofWave SystemMar 14, 2023
70 days to decisionK230019 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Jan 3, 2023
Decision date	Mar 14, 2023
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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