

**K233104 SofWave System**Dec 22, 2023  
87 days to decisionK233104 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233104/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Sep 26, 2023
Decision date	Dec 22, 2023
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233104/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026