

**K230820 SofWave System**Apr 18, 2023  
25 days to decisionK230820 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Mar 24, 2023
Decision date	Apr 18, 2023
Days to decision	25 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/k230820/> 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 13, 2026