

K191421 Sofacia SystemSep 9, 2019
104 days to decisionK191421 · Product code: **OHV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	May 28, 2019
Decision date	Sep 9, 2019
Days to decision	104 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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