

K223237 SofWave SystemDec 16, 2022
58 days to decisionK223237 · Product code: **OHV** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k223237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption (OHV)
Date received	Oct 19, 2022
Decision date	Dec 16, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT05358847****Treatment for Cellulite Appearance**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	69 patients (actual)
Study sites	4 sites
Condition studied	Cellulite
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 1, 2023
Sponsor	Sofwave Medical LTD (Industry)

Primary outcome

Rate of improvement in the appearance of cellulite on the upper thigh/buttock area

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05358847