FDA 510(k) Premarket Notification

CLEARED

K252913 Break Wave

Jan 12, 2026
122 days to decision

K252913 · Product code: **LNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Extracorporeal Shock-wave, Urological (LNS)
Date received	Sep 12, 2025
Decision date	Jan 12, 2026
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sonomotion, Inc.**
Location	San Mateo, CA, US
Contact	Oren Levy
510(k) history	3 submissions · 2 cleared · 2024-2026

CLINICAL EVIDENCE - NCT05701098

SOUND Pivotal Trial - (Sonomotion stOne comminUtion resoNance ultrasounD)

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	64 patients (actual)
Study sites	10 sites
Condition studied	Kidney Stone; Urolithiasis; Nephrolithiasis; Renal Calculi; Kidney Calculi; Nephrolith; Urinary Calculi
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 31, 2025
Sponsor	SonoMotion (Industry)

Primary outcome

Primary Effectiveness Endpoint

Secondary outcome

Secondary safety endpoint

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05701098