FDA 510(k) Premarket Notification

K261086 Break Wave

CLEARED

Apr 29, 2026
28 days to decision

K261086 · Product code: **LNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k261086/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotriptor, Extracorporeal Shock-wave, Urological (LNS)
Date received	Apr 1, 2026
Decision date	Apr 29, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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