

K261086 Break WaveApr 29, 2026
28 days to decisionK261086 · Product code: **LNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k261086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261086/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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