FDA 510(k) Premarket Notification

K262200 Stone Clear (BWSC-LP9-02)

CLEARED

Jul 29, 2026
30 days to decision

K262200 · Product code: **QNA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k262200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ultrasonic Urinary Stone Propulsion Device (QNA)
Date received	Jun 29, 2026
Decision date	Jul 29, 2026
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sonomotion, Inc.**
Location	San Mateo, CA, US
Contact	Emily Hergenreter
Website	https://www.sonomotion.com/
510(k) history	4 submissions · 3 cleared · 2024-2026

Sonomotion, Inc. develops noninvasive platforms for kidney stone treatment. The company specializes in ultrasound-based fragmentation and repositioning technologies designed for office-based procedures on awake patients. Sonomotion operates with a manufacturing facility in San Mateo, California. The company has received FDA 510(k) clearances from total submissions since 2024. Sonomotion focuses exclusively on Gastroenterology & Urology devices, with its most recent clearance in 2026. The company remains actively engaged in regulatory submissions and product development. S...