FDA 510(k) Premarket Notification

K233597 Sonosite LX Ultrasound System

CLEARED

Dec 6, 2023
28 days to decision

K233597 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k233597/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 8, 2023
Decision date	Dec 6, 2023
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**FUJIFILM Sonosite, Inc.**
Location	Bothell, WA, US
Contact	Anoush Frankian
Website	https://www.sonosite.com
510(k) history	25 submissions · 25 cleared · 2013-2026

FUJIFILM Sonosite, Inc. is a portable ultrasound manufacturer based in Bothell, US. The company specializes in point-of-care ultrasound systems for clinical imaging. FUJIFILM Sonosite has received FDA 510(k) clearances from total submissions since 2013. The company's portfolio focuses exclusively on Radiology devices. The latest clearance was in 2026, demonstrating continued regulatory activity and product innovation. The company's cleared devices include portable ultrasound systems designed for diverse clinical settings. Products span multiple system lines, each configur...

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov