

K251830 Sonosite LX Ultrasound SystemJul 10, 2025
27 days to decisionK251830 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k251830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 13, 2025
Decision date	Jul 10, 2025
Days to decision	27 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](https://accessdata.fda.gov)
