

K213763 Sonosite PX Ultrasound System

Dec 27, 2021
26 days to decision

K213763 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k213763/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 1, 2021
Decision date	Dec 27, 2021
Days to decision	26 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)
