

K153626 SonoSite Edge II Ultrasound SystemJan 20, 2016
33 days to decisionK153626 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k153626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 18, 2015
Decision date	Jan 20, 2016
Days to decision	33 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	FUJIFILM Sonosite, Inc.
Location	Bothell, WA, US
Contact	Patricia Liao
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...
