FDA 510(k) Premarket Notification

CLEARED

K162045 SonoSite SII Ultrasound System, SonoSite Edge II Ultrasound System

Aug 18, 2016
24 days to decision

K162045 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k162045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 25, 2016
Decision date	Aug 18, 2016
Days to decision	24 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**FUJIFILM Sonosite, Inc.**
Location	Bothell, WA, US
Contact	Jordan Grimmer
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...