

K152577 ULTRASOUND SYSTEM SONIMAGE HS 1

Oct 8, 2015
29 days to decision

K152577 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k152577/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 9, 2015
Decision date	Oct 8, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Konica Minolta, Inc.
Location	New York, NY, US
Contact	SHIGEYUKI KOJIMA
Website	http://www.konicaminolta.com
510(k) history	25 submissions · 25 cleared · 2014-2025

Konica Minolta, Inc. is a global imaging and technology company with a manufacturing facility in New York, US. The company develops advanced diagnostic and imaging solutions for healthcare and industrial applications. Konica Minolta has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company specializes exclusively in Radiology devices, establishing a focused regulatory portfolio. Its FDA 510(k) clearance history spans from 2014 to 2025, with recent clearances demonstrating continued active development and market engagement...