FDA 510(k) Premarket Notification

CLEARED

K212021 6430 MyLabX75, 6430 MyLab XPro75

Sep 16, 2021
80 days to decision

K212021 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k212021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 28, 2021
Decision date	Sep 16, 2021
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Esaote, S.P.A.**
Location	Genoa, IT
Contact	Alberto Carcagni
Website	https://www.esaote.com
510(k) history	67 submissions · 67 cleared · 2003-2026

Esaote, S.P.A. is a medical diagnostic imaging company based in Genoa, Italy. The company specializes in ultrasound, MRI, and healthcare IT solutions for clinical settings. Esaote has received FDA 510(k) clearances from total submissions since 2003. The company's regulatory portfolio is dominated by Radiology devices, representing 100% of its FDA submissions. Recent cleared devices include the MyLab ultrasound systems and Magnifico Open imaging platforms. The company remains actively engaged in FDA regulatory submissions, with the latest clearance in 2026. Esaote's produc...