FDA 510(k) Premarket Notification

K081386 MODEL 6150 (MYLAB70) AND MODEL 6100 (MYLAB90)

CLEARED

Sep 25, 2008
129 days to decision

K081386 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k081386/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 19, 2008
Decision date	Sep 25, 2008
Days to decision	129 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Esaote, S.P.A.**
Location	Genoa, IT
Contact	Allison Scott
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...