

**K051837 MYLAB 90 ULTRASOUND IMAGING SYSTEM, MODEL 6100**Jul 20, 2005  
14 days to decisionK051837 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k051837/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 6, 2005
Decision date	Jul 20, 2005
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Esaote, S.P.A.</b>
Location	Genoa, IT
Contact	CARRI GRAHAM
Website	<a href="https://www.esaote.com">https://www.esaote.com</a>
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...