FDA 510(k) Premarket Notification

K071996 MYLAB30, MODEL 7300

CLEARED

Aug 3, 2007
8 days to decision

K071996 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k071996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 26, 2007
Decision date	Aug 3, 2007
Days to decision	8 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...