

K162290 MyLabSix CrystaLineOct 14, 2016
60 days to decisionK162290 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k162290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 15, 2016
Decision date	Oct 14, 2016
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Esaote, S.P.A.
Location	Genoa, IT
Contact	MASSIMO POLIGNANO
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...
