

K190989 6400 Ultrasound System (MyLabX6, MyLabX7)May 10, 2019
25 days to decisionK190989 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k190989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 15, 2019
Decision date	May 10, 2019
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Esaote, S.P.A.
Location	Genoa, IT
Contact	Piet de Jong
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...
