

**K183191 6420 Ultrasound System**Dec 4, 2018  
15 days to decisionK183191 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k183191/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 19, 2018
Decision date	Dec 4, 2018
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Esaote, S.P.A.</b>
Location	Genoa, IT
Contact	Massimo Polignano
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...

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