

**K253288 6450 Ultrasound System (MyLabE80)**Apr 6, 2026  
189 days to decisionK253288 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k253288/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 29, 2025
Decision date	Apr 6, 2026
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	6450 Ultrasound System (MyLabE85)

**APPLICANT**

---

Company	<b>Esaote, S.P.A.</b>
Location	Genoa, IT
Contact	Vanessa Ronconi
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...