

K253310 7600 Ultrasound System (MyLabC25)Nov 25, 2025
57 days to decisionK253310 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k253310/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Sep 29, 2025 |
| Decision date | Nov 25, 2025 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | 7600 Ultrasound System (MyLabC30) |

APPLICANT

| | |
|----------------|---|
| Company | Esaote, S.P.A. |
| Location | Genoa, IT |
| Contact | Antonia Perrella |
| 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...