

K100931 MYLABTWICE, MODEL 6200Jun 25, 2010
81 days to decisionK100931 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k100931/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Apr 5, 2010 |
| Decision date | Jun 25, 2010 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Esaote, S.P.A. |
| Location | Genoa, IT |
| Contact | Allison Scott |
| 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...
