

K153277 6200 Ultrasound System and 6250 Ultrasound SystemMay 4, 2016
174 days to decisionK153277 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k153277/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Nov 12, 2015 |
| Decision date | May 4, 2016 |
| Days to decision | 174 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-------------------------------------------------------------|
| Company | Esaote, S.P.A. |
| Location | Genoa, IT |
| Contact | Donatella Ragghianti |
| 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...
