

K161168 MyLabSix Ultrasound SystemSep 2, 2016
129 days to decisionK161168 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k161168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 26, 2016
Decision date	Sep 2, 2016
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Esaote Europe B.V.
Location	Carmel, IN, US
Contact	Bert Vorstenbosch
510(k) history	7 submissions · 7 cleared · 2006-2016

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