

K101605 MYLABONE ULTRASOUND SYSTEMAug 31, 2010
84 days to decisionK101605 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k101605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 8, 2010
Decision date	Aug 31, 2010
Days to decision	84 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026