

K123254 ULTRASOUND SCANNER FLEX FOCUSFeb 13, 2013
118 days to decisionK123254 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k123254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 18, 2012
Decision date	Feb 13, 2013
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B-K Medical Aps
Location	Herlev, DK
Contact	RANDI HAUERBERG
510(k) history	11 submissions · 11 cleared · 2007-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123254/> 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