

**K132335 ULTRASOUND SCANNER FLEX FOCUS 1202**Jan 10, 2014  
168 days to decisionK132335 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k132335/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 26, 2013
Decision date	Jan 10, 2014
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132335/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026