

**K100919 PRO FOCUS 2202, PRO FOCUS 2202 UV MODEL:  
TYPE 2202**Dec 16, 2011  
623 days to decisionK100919 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k100919/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 2, 2010
Decision date	Dec 16, 2011
Days to decision	623 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/k100919/>; 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