

K161960 bk2300Oct 17, 2016
91 days to decisionK161960 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k161960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 18, 2016
Decision date	Oct 17, 2016
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bk Medical Aps
Location	Herlev, DK
Contact	MICHAEL J. DOYLE
510(k) history	9 submissions · 9 cleared · 2015-2023

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