

K222441 Ultrasound System 2300Dec 7, 2022
117 days to decisionK222441 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k222441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 12, 2022
Decision date	Dec 7, 2022
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bk Medical Aps
Location	Herlev, DK
Contact	Sandra Theodoridis
510(k) history	9 submissions · 9 cleared · 2015-2023

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