

K223830 Ultrasound System 2300Apr 11, 2023
111 days to decisionK223830 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k223830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 21, 2022
Decision date	Apr 11, 2023
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223830/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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