

K231764 Ultrasound System 1300Oct 23, 2023
129 days to decisionK231764 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k231764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 16, 2023
Decision date	Oct 23, 2023
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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