

K180737 Ultrasound Scanner System bk2300Aug 1, 2018
132 days to decisionK180737 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k180737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 22, 2018
Decision date	Aug 1, 2018
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180737/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026