

K230185 ANT-X SystemJun 1, 2023
129 days to decisionK230185 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k230185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 23, 2023
Decision date	Jun 1, 2023
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ndr Medical Technology Pte. , Ltd.
Location	Singapore, SG
Contact	Ng Ka Wei
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Alira Health
Contact	Ainoa Forteza

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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