

K243411 Diagnostic X-ray SystemMay 19, 2025
199 days to decisionK243411 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k243411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 1, 2024
Decision date	May 19, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanjing Perlove Medical Equipment Co., Ltd.
Location	Nanjing, CN
Contact	Fengfang Lu
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	APlus Healthcare Technology (Shanghai) Co., Ltd.
Contact	Jack Fang

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

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