

K233200 XPLUS 35 Series (XPLUS 35, XPLUS 35FD)Nov 16, 2023
49 days to decisionK233200 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k233200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 28, 2023
Decision date	Nov 16, 2023
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GEMSS HEALTHCARE CO., LTD.
Location	Paju-Si, KR
Contact	Jiho Park
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Mtech Group, LLC
Contact	Dave Kim

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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