FDA 510(k) Premarket Notification

K233200 XPLUS 35 Series (XPLUS 35, XPLUS 35FD)

CLEARED

Nov 16, 2023
49 days to decision

K233200 · 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