K230800 XVISION-525, HORIZON, HI-300, HI-500, SATURN-F PF32, SATURN-F PF40, SATURN-F PF50

CLEARED

Nov 2, 2023
224 days to decision

K230800 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k230800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 23, 2023
Decision date	Nov 2, 2023
Days to decision	224 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