

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

Nov 2, 2023  
224 days to decision

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

**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k230800/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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