

**K232178 GXR-ES/ECS Diagnostic X-Ray System, (Models GXR-ES series, GXR-ECS series)**Sep 19, 2023  
57 days to decisionK232178 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k232178/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 24, 2023
Decision date	Sep 19, 2023
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DRGEM Corporation</b>
Location	Echo, OR, US
Contact	Park Sunghee
510(k) history	13 submissions · 13 cleared · 2010-2025

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