

**K242019 GXR-Series Diagnostic X-Ray System**Jan 7, 2025  
181 days to decisionK242019 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k242019/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 10, 2024
Decision date	Jan 7, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242019/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026