

K192364 GXR-Series Diagnostic X-Ray SystemSep 26, 2019
27 days to decisionK192364 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k192364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Aug 30, 2019
Decision date	Sep 26, 2019
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DRGEM Corporation
Location	Echo, OR, US
Contact	Ki-Nam Yang
510(k) history	13 submissions · 13 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192364/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026