

**K192453 DIAMOND-5A/6A/8A**Oct 1, 2019  
22 days to decisionK192453 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k192453/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 9, 2019
Decision date	Oct 1, 2019
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192453/> 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 26, 2026