

**K214012 Straight Arm DDR**Jan 12, 2022  
21 days to decisionK214012 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k214012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 22, 2021
Decision date	Jan 12, 2022
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Konica Minolta Healthcare Americas, Inc.</b>
Location	Garner, NC, US
Contact	Jan Maniscalco
510(k) history	5 submissions · 5 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214012/> 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