

**K162529 DigiX FDX**Mar 3, 2017  
175 days to decisionK162529 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k162529/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 9, 2016
Decision date	Mar 3, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Allengers Medical Systems Limited</b>
Location	Derabassi, Distt Mohali, IN
Contact	Manmohan Singh
510(k) history	7 submissions · 7 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162529/> 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