

**K152813 FS-500DDR Medical Radiographic X-Ray System**Dec 2, 2016  
431 days to decisionK152813 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k152813/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 28, 2015
Decision date	Dec 2, 2016
Days to decision	431 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orich Medical Equipment (Tianjin Co., Ltd.</b>
Location	Miami, FL, US
Contact	JU PENG
510(k) history	2 submissions · 2 cleared · 2012-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152813/> 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 16, 2026