

**K110828 DDRELEMENT**Aug 23, 2011  
152 days to decisionK110828 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k110828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 24, 2011
Decision date	Aug 23, 2011
Days to decision	152 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Swissray Medical AG</b>
Location	Elizabeth, NJ, US
Contact	JOHN MONAHAN
510(k) history	4 submissions · 4 cleared · 2005-2013

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