

**K133496 X TWIN SYSTEM**Dec 3, 2014  
384 days to decisionK133496 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k133496/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 14, 2013
Decision date	Dec 3, 2014
Days to decision	384 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roesys GmbH</b>
Location	Espelkamp, Nordrhein-Westfalen, DE
Contact	JOCHEN DYSZBALIS
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133496/> 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