

**K133695 TITAN 11**Aug 7, 2014  
247 days to decisionK133695 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k133695/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 3, 2013
Decision date	Aug 7, 2014
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gemss Medical Systems Co., Ltd.</b>
Location	Houston, TX, US
Contact	DAVE KIM
510(k) history	4 submissions · 4 cleared · 2014-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133695/> 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