

**K161966 PerkinElmer XRpad2 4336 HWC-M Flat Panel Detector**Sep 8, 2016  
52 days to decisionK161966 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k161966/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jul 18, 2016
Decision date	Sep 8, 2016
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Perkinelmer, Inc.</b>
Location	Indianapolis, IN, US
Contact	Dawn Spooner
Website	<a href="http://www.perkinelmer.com">http://www.perkinelmer.com</a>
510(k) history	17 submissions · 15 cleared · 2009-2022

PerkinElmer, Inc. is a global provider of laboratory instruments, reagents, and analytical solutions. The company operates with a manufacturing facility in Indianapolis, US, and specializes in chemistry devices for clinical diagnostics and research applications. PerkinElmer received FDA 510(k) clearances from total submissions between 2009 and 2022. The company's cleared devices focus primarily on neonatal screening and mass spectrometry chemistry kits, along with diagnostic instrumentation. This regulatory record reflects the company's established presence in clinical la...

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