

K161942 PerkinElmer, XRpad2 3025 HWC-M Flat Panel DetectorSep 1, 2016
48 days to decisionK161942 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k161942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jul 15, 2016
Decision date	Sep 1, 2016
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Perkinelmer, Inc.
Location	Indianapolis, IN, US
Contact	Dawn Spooner
Website	http://www.perkinelmer.com
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...
