

**K122495 PERKINELMER XRD 1622 AP3 MED FLAT PANEL  
DETECTOR**Nov 28, 2012  
104 days to decisionK122495 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k122495/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received         | Aug 16, 2012   |
| Decision date         | Nov 28, 2012   |
| Days to decision      | 104 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Perkinelmer, Inc.</b>  |
| Location       | Indianapolis, IN, US  |
| Contact        | KAY A TAYLOR  |
| 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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