

K121095 DX-D IMAGING PACKAGEAug 16, 2012
127 days to decisionK121095 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k121095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Apr 11, 2012
Decision date	Aug 16, 2012
Days to decision	127 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Agfa Healthcare N.V.
Location	Mortsel, BE
Contact	DAVID LEDWIG
510(k) history	27 submissions · 27 cleared · 2009-2025

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