

K161368 DX-D Imaging Package (DR 10s), DX-D Imaging Package (DR 14s), DX-D Imaging Package (DR 14s)Sep 22, 2016
128 days to decisionK161368 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k161368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 17, 2016
Decision date	Sep 22, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161368/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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