

K131408 CR 12-X DIGITIZERAug 29, 2013
106 days to decisionK131408 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k131408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 15, 2013
Decision date	Aug 29, 2013
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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