

K211790 DX-D Imaging Package with XD DetectorsJul 30, 2021
50 days to decisionK211790 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k211790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jun 10, 2021
Decision date	Jul 30, 2021
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Agfa N.V.
Location	Mortsel, BE
Contact	Wim Govaerts
510(k) history	6 submissions · 6 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Agfa US Corp.
Contact	ShaeAnn Cavanagh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211790/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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