

K212145 DR 800 with DSA, DR 800Aug 31, 2021
53 days to decisionK212145 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k212145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jul 9, 2021
Decision date	Aug 31, 2021
Days to decision	53 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](https://accessdata.fda.gov)

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