FDA 510(k) Premarket Notification

K212145 DR 800 with DSA, DR 800

CLEARED

Aug 31, 2021
53 days to decision

K212145 · 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