FDA 510(k) Premarket Notification

K213469 VALORY

CLEARED

Nov 18, 2021
21 days to decision

K213469 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k213469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Oct 28, 2021
Decision date	Nov 18, 2021
Days to decision	21 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