

K191884 DR 100sAug 9, 2019
25 days to decisionK191884 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k191884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 15, 2019
Decision date	Aug 9, 2019
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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