

K193262 DR 600 with TomosynthesisMar 9, 2020
104 days to decisionK193262 · Product code: **IZF** · Radiology
Source: <https://www.510kdatabase.net/k193262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Nov 26, 2019
Decision date	Mar 9, 2020
Days to decision	104 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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