

K183275 DR 800 with TomosynthesisFeb 1, 2019
70 days to decisionK183275 · Product code: **IZF** · Radiology
Source: <https://www.510kdatabase.net/k183275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Nov 23, 2018
Decision date	Feb 1, 2019
Days to decision	70 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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