

K180589 DR 800 with MUSICA DynamicApr 5, 2018
30 days to decisionK180589 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k180589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Mar 6, 2018
Decision date	Apr 5, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Agfa Healthcare N.V.
Location	Mortsel, BE
Contact	Wim Govaerts
510(k) history	27 submissions · 27 cleared · 2009-2025

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