

K122768 GENESISJan 18, 2013
130 days to decisionK122768 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k122768/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Sep 10, 2012
Decision date	Jan 18, 2013
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dornier Medtech America, Inc.
Location	Marietta, GA, US
Contact	JOHN J SMITH
510(k) history	40 submissions · 40 cleared · 1990-2023

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