

K133434 GENESIS IINov 26, 2014
383 days to decisionK133434 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k133434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Nov 8, 2013
Decision date	Nov 26, 2014
Days to decision	383 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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