

K884578 POLARIX 2 AND POLARIX 2EFeb 9, 1989
100 days to decisionK884578 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k884578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Nov 1, 1988
Decision date	Feb 9, 1989
Days to decision	100 days
Third-party review	No

APPLICANT

Company	Dyna-Med
Location	Mchenry, IL, US
Contact	THOMAS, JR
510(k) history	4 submissions · 3 cleared · 1976-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884578/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026