

K811094 CARDIAC 1000 TMJul 28, 1981
98 days to decisionK811094 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k811094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Apr 21, 1981
Decision date	Jul 28, 1981
Days to decision	98 days
Third-party review	No

APPLICANT

Company	American Edwards Laboratories
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987

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Device record: <https://www.510kdatabase.net/k811094/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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