

**K964991 700-FR SERIES RADIOLUCENT STIMULATION
ELECTRODES**Jan 15, 1997
33 days to decisionK964991 · Product code: **MKJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k964991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Dec 13, 1996
Decision date	Jan 15, 1997
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cardiotronics Systems, Inc.
Location	Carlsbad, CA, US
Contact	TIM J WAY
510(k) history	4 submissions · 4 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964991/> 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 July 4, 2026