FDA 510(k) Premarket Notification

K964991 700-FR SERIES RADIOLUCENT STIMULATION ELECTRODES

CLEARED

Jan 15, 1997
33 days to decision

K964991 · 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