FDA 510(k) Premarket Notification

K980857 MEDI-TRACE 1310P COMBINATION DEFIBRILLATION, MONITORING & PACING ELECTRODE

CLEARED

May 12, 1998
68 days to decision

K980857 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k980857/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Mar 5, 1998
Decision date	May 12, 1998
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Graphic Controls Corp.**
Location	Mchenry, IL, US
Contact	KATHLEEN SELOVER
510(k) history	55 submissions · 55 cleared · 1977-1998