FDA 510(k) Premarket Notification

K850156 ECG PATIENT MONITOR 301

CLEARED

Mar 1, 1985
45 days to decision

K850156 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k850156/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jan 15, 1985
Decision date	Mar 1, 1985
Days to decision	45 days
Third-party review	No

APPLICANT

Company	**Rigel Medical Electronics, Inc.**
Location	Mill Valley, CA, US
Contact	MICHAEL E FEWER
510(k) history	6 submissions · 6 cleared · 1984-1989