FDA 510(k) Premarket Notification

K823312 CADIO-RESPIRATORY MONITOR #CR-2

CLEARED

Nov 30, 1982
25 days to decision

K823312 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k823312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Nov 5, 1982
Decision date	Nov 30, 1982
Days to decision	25 days
Third-party review	No

APPLICANT

Company	**Electromed Intl., Ltd.**
Location	Mchenry, IL, US
510(k) history	23 submissions · 23 cleared · 1981-2001