FDA 510(k) Premarket Notification

K822952 560

CLEARED

Nov 1, 1982
28 days to decision

K822952 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k822952/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Oct 4, 1982
Decision date	Nov 1, 1982
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Kone Instruments, Inc.**
Location	Mchenry, IL, US
510(k) history	12 submissions · 12 cleared · 1982-1987