FDA 510(k) Premarket Notification

K830433 PATIENT MONITOR 575

CLEARED

Mar 24, 1983
43 days to decision

K830433 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k830433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Feb 9, 1983
Decision date	Mar 24, 1983
Days to decision	43 days
Third-party review	No

APPLICANT

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