FDA 510(k) Premarket Notification

K831817 PATIENT MONITOR #RM-100

CLEARED

Oct 31, 1983
147 days to decision

K831817 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k831817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jun 6, 1983
Decision date	Oct 31, 1983
Days to decision	147 days
Third-party review	No

APPLICANT

Company	**Honeywell, Inc.**
Location	Mchenry, IL, US
510(k) history	69 submissions · 69 cleared · 1976-1990

Honeywell, Inc. is an American multinational conglomerate headquartered in Charlotte, North Carolina. The company operates across aerospace, building automation, industrial automation, and energy solutions. Honeywell's medical device regulatory history spans from 1976 to 1990. The company received FDA 510(k) clearances from total submissions. Cardiovascular devices represented the dominant focus, accounting for approximately 75% of submissions. This historical record reflects the company's past involvement in patient monitoring systems, defibrillators, and related cardiov...