FDA 510(k) Premarket Notification

K851496 ECG MONITOR MODEL RM102

CLEARED

Jul 24, 1985
100 days to decision

K851496 · Product code: **DXJ** · Cardiovascular
Source: https://www.510kdatabase.net/k851496/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Cathode-ray Tube, Medical (DXJ)
Date received	Apr 15, 1985
Decision date	Jul 24, 1985
Days to decision	100 days
Third-party review	No

APPLICANT

Company	**Honeywell, Inc.**
Location	Mchenry, IL, US
Contact	MARTIN KUTIK
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...