FDA 510(k) Premarket Notification

K863100 CEN STA MON AC/DC ALARM CENTRAL ACCES ALARM RECOR

CLEARED

Feb 3, 1987
174 days to decision

K863100 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k863100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 13, 1986
Decision date	Feb 3, 1987
Days to decision	174 days
Third-party review	No

APPLICANT

Company	**Honeywell, Inc.**
Location	Mchenry, IL, US
Contact	STEVE BRODY
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...