FDA 510(k) Premarket Notification

K855125 PHYSIOLOGICAL TELEMETRY PATIENT MONITORING SYSTEM

CLEARED

Mar 26, 1986
93 days to decision

K855125 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k855125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Dec 23, 1985
Decision date	Mar 26, 1986
Days to decision	93 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k855125/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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