FDA 510(k) Premarket Notification

CLEARED

K921014 MODEL M2350A AND M2360A WAVEVUE CENTRAL MONITOR

Oct 1, 1992
212 days to decision

K921014 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k921014/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Mar 3, 1992
Decision date	Oct 1, 1992
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hewlett-Packard Co.**
Location	Mchenry, IL, US
Contact	DAVID OSBORN
Website	https://www.hp.com
510(k) history	230 submissions · 229 cleared · 1976-2000

Hewlett-Packard Co. is a technology company headquartered in McHenry, US. The company historically developed medical devices alongside its core computing and printing business. Hewlett-Packard received FDA 510(k) clearances from total submissions, with clearances spanning 1976 to 2000. The company specialized in cardiovascular devices, including defibrillators, telemetry systems, and clinical information systems. Additional cleared devices covered gastroenterology, urology, and radiology applications. This regulatory record reflects the company's historical involvement in...