FDA 510(k) Premarket Notification

K920429 MODIFIED MODEL M1403A TELEMETRY MONITORING SYSTEM

CLEARED

Jul 20, 1993
533 days to decision

K920429 · Product code: **MLD** · Cardiovascular
Source: https://www.510kdatabase.net/k920429/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, St Segment With Alarm (MLD)
Date received	Feb 3, 1992
Decision date	Jul 20, 1993
Days to decision	533 days
Third-party review	No
Summary / Statement	Statement

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...