FDA 510(k) Premarket Notification

CLEARED

K950821 HP M1205A OMNICARE COMPONENT TRANSPORT MONITORING SYSTEM MODEL 24

Oct 3, 1995
222 days to decision

K950821 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k950821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Feb 23, 1995
Decision date	Oct 3, 1995
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hewlett-Packard Co.**
Location	Mchenry, IL, US
Contact	RAY STELTING
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...