FDA 510(k) Premarket Notification

CLEARED

K974420 M1730B TRACEMASTER ECG SYSTEM, M1766B LOCAL EDIT STATION, M1798B REMOTE EDIT STATION

Feb 19, 1998
87 days to decision

K974420 · Product code: **DSH** · Cardiovascular
Source: https://www.510kdatabase.net/k974420/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Nov 24, 1997
Decision date	Feb 19, 1998
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hewlett-Packard Co.**
Location	Mchenry, IL, US
Contact	STEVEN A CLARKE
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...