

K954980 PAGERWRITER 200, 200I CARDIOGRAPH & INTERPRETIVE CARDIOMay 15, 1996
197 days to decisionK954980 · Product code: **LOS** · Cardiovascular
Source: <https://www.510kdatabase.net/k954980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Oct 31, 1995
Decision date	May 15, 1996
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hewlett-Packard Co.
Location	McHenry, IL, US
Contact	NANCY WINN
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...

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