

**K910291 MODEL 43420B NEWWAVE HOLTER
SYSTEM/MODIFICATION**Apr 22, 1991
89 days to decisionK910291 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k910291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jan 23, 1991
Decision date	Apr 22, 1991
Days to decision	89 days
Third-party review	No

APPLICANT

Company	Hewlett-Packard Co.
Location	Mchenry, IL, US
Contact	MONICA FERRANTE
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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