

K853669 MODEL 43400A REAL-TIME AMBULATORY ECG MONITOR ANALMar 31, 1986
209 days to decisionK853669 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k853669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Sep 3, 1985
Decision date	Mar 31, 1986
Days to decision	209 days
Third-party review	No

APPLICANT

Company	Hewlett-Packard Co.
Location	Mchenry, IL, US
Contact	RICHARD W STRAYER
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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