FDA 510(k) Premarket Notification

K853769 IRREGULAR CURVE TRACING REVISITION & DOPPLER

CLEARED

Oct 31, 1985
52 days to decision

K853769 · Product code: **DXK** · Cardiovascular
Source: https://www.510kdatabase.net/k853769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Echocardiograph (DXK)
Date received	Sep 9, 1985
Decision date	Oct 31, 1985
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Hewlett-Packard Co.**
Location	Mchenry, IL, US
Contact	JOSEPH M LUSZEZ
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...