FDA 510(k) Premarket Notification

K913827 MODEL 7700A/77010A/77025A/77030A/77035A ULTRA IMAG

CLEARED

Nov 19, 1991
85 days to decision

K913827 · Product code: **DPW** · Radiology
Source: https://www.510kdatabase.net/k913827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Aug 26, 1991
Decision date	Nov 19, 1991
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hewlett-Packard Co.**
Location	Mchenry, IL, US
Contact	CHARLES R BURR
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...