FDA 510(k) Premarket Notification

K791343 MODEL 1338A CRT DISPLAY

CLEARED

Sep 17, 1979
68 days to decision

K791343 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k791343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 11, 1979
Decision date	Sep 17, 1979
Days to decision	68 days
Third-party review	No

APPLICANT

Company	**Hewlett-Packard Co.**
Location	Mchenry, IL, US
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...