FDA 510(k) Premarket Notification

K892354 ODIS - OBSTETRICAL DISPLAY INFO SYSTEM, HP M1370A

CLEARED

Aug 8, 1989
151 days to decision

K892354 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k892354/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 10, 1989
Decision date	Aug 8, 1989
Days to decision	151 days
Third-party review	No

APPLICANT

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