FDA 510(k) Premarket Notification

CLEARED

K885316 DISPOSABLE INTRAUTERINE PRESSURE KIT MODEL 13972A

Mar 23, 1989
84 days to decision

K885316 · Product code: **KXO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k885316/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Dec 29, 1988
Decision date	Mar 23, 1989
Days to decision	84 days
Third-party review	No

APPLICANT

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