FDA 510(k) Premarket Notification

K972348 HP ENDOVAGINAL/ENDORECTAL PROBE, HP IMAGE POINT ULTRASOUND SYSTEM

CLEARED

Jul 24, 1997
30 days to decision

K972348 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k972348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jun 24, 1997
Decision date	Jul 24, 1997
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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