

K970034 SD 800 SONODIAGNOST ULTRASOUND IMAGING SYSTEMMar 17, 1997
73 days to decisionK970034 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k970034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jan 3, 1997
Decision date	Mar 17, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hewlett-Packard Co.
Location	Mchenry, IL, US
Contact	PAUL SCHRADER
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...

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