FDA 510(k) Premarket Notification

K830753 NEEDLE GUIDE MODEL 21285A

CLEARED

Jun 16, 1983
98 days to decision

K830753 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k830753/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Mar 10, 1983
Decision date	Jun 16, 1983
Days to decision	98 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...