FDA 510(k) Premarket Notification

K896437 KONTRON SIGMA 44 HVCD ULTRASOUND IMAGING SYSTEM

CLEARED

Dec 3, 1990
389 days to decision

K896437 · Product code: **DPT** · Cardiovascular
Source: https://www.510kdatabase.net/k896437/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Blood-flow, Extravascular (DPT)
Date received	Nov 9, 1989
Decision date	Dec 3, 1990
Days to decision	389 days
Third-party review	No

APPLICANT

Company	**Kontron Instruments, Inc.**
Location	Mchenry, IL, US
Contact	DAVID CROMWICK
510(k) history	57 submissions · 57 cleared · 1981-1993

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k896437/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026