FDA 510(k) Premarket Notification

K943200 FLOSCOPE SUPER VASCULAR LAB

CLEARED

Nov 21, 1995
504 days to decision

K943200 · Product code: **JAF** · Radiology
Source: https://www.510kdatabase.net/k943200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Nonfetal (JAF)
Date received	Jul 5, 1994
Decision date	Nov 21, 1995
Days to decision	504 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Advance Medical Device, Inc.**
Location	Ontario L3y 4v8, Canada, CA
Contact	DAVID LERNER
510(k) history	5 submissions · 5 cleared · 1990-1997