FDA 510(k) Premarket Notification

K942852 RESPITRACE PT

CLEARED

Feb 13, 1996
610 days to decision

K942852 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k942852/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jun 13, 1994
Decision date	Feb 13, 1996
Days to decision	610 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Non-Invasive Monitoring Systems, Inc.**
Location	Washington, DC, US
Contact	MARISA COYLE
Website	http://www.nims-inc.com
510(k) history	6 submissions · 6 cleared · 1989-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k942852/ 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 26, 2026