FDA 510(k) Premarket Notification

K974581 MILLENNIA 3500 SERIES MONITOR WITH ANTHESTHETIC AGENT

CLEARED

Oct 28, 1998
324 days to decision

K974581 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k974581/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Dec 8, 1997
Decision date	Oct 28, 1998
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invivo Research, Inc.**
Location	Orlando, FL, US
Contact	FRANCIS CASEY
510(k) history	14 submissions · 14 cleared · 1989-2005