FDA 510(k) Premarket Notification

K935020 OMNI-TRAC MODIFICATION

CLEARED

Apr 26, 1995
553 days to decision

K935020 · Product code: **MLD** · Cardiovascular
Source: https://www.510kdatabase.net/k935020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, St Segment With Alarm (MLD)
Date received	Oct 20, 1993
Decision date	Apr 26, 1995
Days to decision	553 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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