

K935020 OMNI-TRAC MODIFICATIONApr 26, 1995
553 days to decisionK935020 · 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

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