

K953175 AS/3 ESTPR MODULEFeb 6, 1997
580 days to decisionK953175 · Product code: **MLD** · Cardiovascular
Source: <https://www.510kdatabase.net/k953175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, St Segment With Alarm (MLD)
Date received	Jul 7, 1995
Decision date	Feb 6, 1997
Days to decision	580 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Datex Division Instrumentarium Corp.
Location	Walker, MI, US
Contact	VINCENT RAUSHER
510(k) history	55 submissions · 55 cleared · 1982-1997

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