

**K981378 DATEX-ENGSTROM LIGHT MONITOR MODELS F-LM1,
F-LMP1**

Nov 3, 1998
201 days to decision

K981378 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k981378/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Apr 16, 1998
Decision date	Nov 3, 1998
Days to decision	201 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Datex-Engstrom, Inc.
Location	Tewksbury, MA, US
Contact	JOEL C KENT
510(k) history	9 submissions · 9 cleared · 1998-1998

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Device record: <https://www.510kdatabase.net/k981378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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