

**K944257 LIONHEART 3 MULTI-PARAMETER SIMULATOR**Sep 21, 1994  
21 days to decisionK944257 · Product code: **DRT** · CardiovascularSource: <https://www.510kdatabase.net/k944257/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 31, 1994
Decision date	Sep 21, 1994
Days to decision	21 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bio-Tek Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	MICHAEL N SEVIGNY
510(k) history	37 submissions · 35 cleared · 1980-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944257/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 21, 2026