

**K934644 K3 SYSTEM**Nov 1, 1994  
398 days to decisionK934644 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k934644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Sep 29, 1993
Decision date	Nov 1, 1994
Days to decision	398 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Astro-Med, Inc.</b>
Location	West Warwick, RI, US
Contact	MICHAEL SULLIVAN
510(k) history	13 submissions · 13 cleared · 1989-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934644/> 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 June 24, 2026