

**K972408 CARDIAC STATUS CONTROLS**Jul 25, 1997  
29 days to decisionK972408 · Product code: **JJT** · Chemistry  
Source: <https://www.510kdatabase.net/k972408/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Jun 26, 1997
Decision date	Jul 25, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Spectral Diagnostics, Inc.</b>
Location	Toronto, Ontario, CA
Contact	FRANCEE S BOCHES
510(k) history	12 submissions · 11 cleared · 1997-2006

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