

**K030057 SPECTRAL CARDIAC STATUS CK-MB/MYOGLOBIN/TROPONIN I 3-IN-1 TEST**Mar 19, 2003  
71 days to decisionK030057 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k030057/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jan 7, 2003
Decision date	Mar 19, 2003
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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