

K014105 SPECTRAL'S TROPONIN IFeb 1, 2002
50 days to decisionK014105 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k014105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Dec 13, 2001
Decision date	Feb 1, 2002
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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