

K992127 CARDIOQUANT TROPONIN I TESTOct 4, 1999
103 days to decisionK992127 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k992127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jun 23, 1999
Decision date	Oct 4, 1999
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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