

K022409 SPECTRAL'S CARDIAC STATUS CK-MB RAPID TEST

Sep 30, 2002
68 days to decision

K022409 · Product code: JHT · Chemistry
Source: <https://www.510kdatabase.net/k022409/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Cpk Isoenzymes (JHT)
Date received	Jul 24, 2002
Decision date	Sep 30, 2002
Days to decision	68 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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Device record: <https://www.510kdatabase.net/k022409/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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