

K972687 CARDIAC STATUS CONTROLS/TROPONIN IJul 28, 1997
11 days to decisionK972687 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k972687/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Jul 17, 1997 |
| Decision date | Jul 28, 1997 |
| Days to decision | 11 days |
| Third-party review | No |
| Summary / Statement | Statement |

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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