

**K973126 TRIAGE CARDIAC PANEL, TRIAGE TROPONIN-I,
TRIASGE CK-MB, TRIAGE MYOGLOBIN, TRIAGE TROPONIN-I
AND CK-MB, TRIAGE TROPONIN-I**Oct 6, 1997
47 days to decisionK973126 · Product code: **JHX** · Chemistry
Source: <https://www.510kdatabase.net/k973126/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fluorometric Method, Cpk Or Isoenzymes (JHX) |
| Date received | Aug 20, 1997 |
| Decision date | Oct 6, 1997 |
| Days to decision | 47 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Biosite Incorporated |
| Location | San Diego, CA, US |
| Contact | JOHN F BRUNI |
| 510(k) history | 46 submissions · 45 cleared · 1990-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973126/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026