

**K981882 CARDIAC STATUS CK-MB/MYOGLOBIN/TROPONIN I
RAPID TEST**Jul 6, 1998
39 days to decisionK981882 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k981882/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunoassay Method, Troponin Subunit (MMI) |
| Date received | May 28, 1998 |
| Decision date | Jul 6, 1998 |
| Days to decision | 39 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Princeton BioMeditech Corp. |
| Location | Monmouth Junction, NJ, US |
| Contact | JEMO KANG |
| 510(k) history | 72 submissions · 72 cleared · 1994-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981882/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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