

**K991299 MODIFICATION TO CARDIAC STATUS CK-MB/MYOGLOBIN RAPID ONE-STEP TEST, LIFESIGN MI CK-MB/MYOGLOBIN, LIFESIGN CK-MB/MYOGLOBI**May 28, 1999  
52 days to decisionK991299 · Product code: JHT · Chemistry  
Source: <https://www.510kdatabase.net/k991299/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Chromatographic Separation, Cpk Isoenzymes (JHT) |
| Date received         | Apr 6, 1999                                      |
| Decision date         | May 28, 1999                                     |
| Days to decision      | 52 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991299/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026