

K984433 QUANTECH CK-MB ASSAYNov 1, 1999
322 days to decisionK984433 · Product code: **MYT** · Chemistry
Source: <https://www.510kdatabase.net/k984433/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Biosensor, Immunoassay, Cpk Or Isoenzymes (MYT) |
| Date received | Dec 14, 1998 |
| Decision date | Nov 1, 1999 |
| Days to decision | 322 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Quantech , Ltd. |
| Location | Northridge, CA, US |
| Contact | ROBIN J HELLEN |
| 510(k) history | 3 submissions · 3 cleared · 1999-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984433/> 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 June 30, 2026