

K844468 TRIGLYCERIDE CALIBRATORDec 11, 1984
22 days to decisionK844468 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k844468/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Secondary (JIT) |
| Date received | Nov 19, 1984 |
| Decision date | Dec 11, 1984 |
| Days to decision | 22 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Sigma Diagnostics, Inc. |
| Location | Mchenry, IL, US |
| Contact | MATHEW MADAPPALLY |
| 510(k) history | 164 submissions · 164 cleared · 1984-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k844468/>; 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