

K041578 QUICKSCREEN, MODELS 9177X AND 9178XSep 10, 2004
88 days to decisionK041578 · Product code: **LCM** · Chemistry
Source: <https://www.510kdatabase.net/k041578/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Enzyme Immunoassay, Phencyclidine (LCM) |
| Date received | Jun 14, 2004 |
| Decision date | Sep 10, 2004 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Phamatech |
| Location | San Diego, CA, US |
| Contact | CARL MONGIOVI |
| 510(k) history | 47 submissions · 47 cleared · 1996-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041578/> 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 28, 2026