

K864041 EMDS THEOPHYLLINE TESTPACKS ITEM #67662/95Nov 25, 1986
40 days to decisionK864041 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k864041/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Theophylline (KLS) |
| Date received | Oct 16, 1986 |
| Decision date | Nov 25, 1986 |
| Days to decision | 40 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Em Diagnostic Systems, Inc. |
| Location | Walker, MI, US |
| Contact | RAYMOND L MILLER |
| 510(k) history | 288 submissions · 288 cleared · 1984-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864041/>, 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