

**K855227 MICRO-EIA THEOPHYLLINE TEST KIT MONOCLONAL**Apr 11, 1986  
102 days to decisionK855227 · Product code: **KLS** · Toxicology  
Source: <https://www.510kdatabase.net/k855227/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Enzyme Immunoassay, Theophylline (KLS) |
| Date received         | Dec 30, 1985                           |
| Decision date         | Apr 11, 1986                           |
| Days to decision      | 102 days                               |
| Third-party review    | No                                     |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Bioclinical Systems, Inc.</b>        |
| Location       | St.Louis, MO, US                        |
| Contact        | BRUCE F WATKINS                         |
| 510(k) history | 13 submissions · 13 cleared · 1985-1995 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k855227/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026