

K850856 ICS THEOPHYLLINE REAGENTSMar 29, 1985
28 days to decisionK850856 · Product code: **KLS** · Chemistry
Source: <https://www.510kdatabase.net/k850856/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Theophylline (KLS) |
| Date received | Mar 1, 1985 |
| Decision date | Mar 29, 1985 |
| Days to decision | 28 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Beckman Instruments, Inc. |
| Location | Mchenry, IL, US |
| Contact | JACK E SOROKIN |
| Website | https://www.beckman.com |
| 510(k) history | 281 submissions · 281 cleared · 1976-1998 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850856/> 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 22, 2026