

K884358 CEDIA THEOPHYLLINE ASSAYFeb 7, 1989
113 days to decisionK884358 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k884358/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Theophylline (KLS) |
| Date received | Oct 17, 1988 |
| Decision date | Feb 7, 1989 |
| Days to decision | 113 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Microgenics Corp. |
| Location | Concord, CA, US |
| Contact | ROBERT K PIGOZZI |
| 510(k) history | 107 submissions · 106 cleared · 1985-2013 |

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