

**K864409 IMPULSE COATED TUBE THEOPHYLLINE ASSAY
REAGENTS**Dec 22, 1986
42 days to decisionK864409 · Product code: LER · Toxicology
Source: <https://www.510kdatabase.net/k864409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Theophylline (LER)
Date received	Nov 10, 1986
Decision date	Dec 22, 1986
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Sclavo, Inc.
Location	Mchenry, IL, US
Contact	MICHAEL BRINKLEY
510(k) history	82 submissions · 82 cleared · 1977-1992

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