

K865000 IMPULSE COATED TUBE PHENOBARBITAL ASSAY REAGENTS

Feb 6, 1987
46 days to decision

K865000 · Product code: **LET** · Toxicology
Source: <https://www.510kdatabase.net/k865000/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Phenobarbital (LET)
Date received	Dec 22, 1986
Decision date	Feb 6, 1987
Days to decision	46 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k865000/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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