

**K865102 IMPULSE COATED TUBE PHENYTOIN ASSAY
REAGENTS**Jan 13, 1987
20 days to decisionK865102 · Product code: **LES** · Toxicology
Source: <https://www.510kdatabase.net/k865102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Diphenylhydantoin (LES)
Date received	Dec 24, 1986
Decision date	Jan 13, 1987
Days to decision	20 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.netDevice record: <https://www.510kdatabase.net/k865102/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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