

K862554 IMPULSE PHENYTOIN ASSAY REAGENTJul 16, 1986
13 days to decisionK862554 · Product code: **LGR** · Toxicology
Source: <https://www.510kdatabase.net/k862554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Jul 3, 1986
Decision date	Jul 16, 1986
Days to decision	13 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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