

K842586 PHENYTOIN KIT FLUORESCENCE POLARIZATIONSep 26, 1984
85 days to decisionK842586 · Product code: **LGR** · Immunology
Source: <https://www.510kdatabase.net/k842586/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Jul 3, 1984
Decision date	Sep 26, 1984
Days to decision	85 days
Third-party review	No

APPLICANT

Company	Windsor Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1981-1987

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Device record: <https://www.510kdatabase.net/k842586/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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