

K955562 INNOFLUOR PHENYTOIN ASSAY SYSTEMJan 24, 1996
49 days to decisionK955562 · Product code: **LGR** · Toxicology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Dec 6, 1995
Decision date	Jan 24, 1996
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oxis Intl., Inc.
Location	Portland, OR, US
Contact	LYNDA M TAYLOR
510(k) history	11 submissions · 11 cleared · 1995-1997

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