

K934388 QMS PHENOBARBITALFeb 25, 1994
169 days to decisionK934388 · Product code: **LFN** · Toxicology
Source: <https://www.510kdatabase.net/k934388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nephelometric Inhibition Immunoassay, Phenobarbital (LFN)
Date received	Sep 9, 1993
Decision date	Feb 25, 1994
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seradyn, Inc.
Location	Indianapolis, IN, US
Contact	ANDRIS INDRIKSONS
510(k) history	28 submissions · 28 cleared · 1988-2007

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