

K070645 SERADYN QMS TOPIRAMATEMay 17, 2007
70 days to decisionK070645 · Product code: **NWM** · Toxicology
Source: <https://www.510kdatabase.net/k070645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay, Anti-seizure Drug (NWM)
Date received	Mar 8, 2007
Decision date	May 17, 2007
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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