

K051211 QMS ZONISAMIDE REAGENTS, CALIBRATORS AND CONTROLSNov 18, 2005
191 days to decisionK051211 · Product code: **NWM** · Chemistry
Source: <https://www.510kdatabase.net/k051211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay, Anti-seizure Drug (NWM)
Date received	May 11, 2005
Decision date	Nov 18, 2005
Days to decision	191 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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