

**K062966 QMS LAMOTRIGINE ASSAY (REAGENTS),
CALIBRATORS & CONTROLS**Jan 12, 2007
105 days to decisionK062966 · Product code: **ORH** · Chemistry
Source: <https://www.510kdatabase.net/k062966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lamotrigine Assay (ORH)
Date received	Sep 29, 2006
Decision date	Jan 12, 2007
Days to decision	105 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062966/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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