

K061549 AMNIOSTAT-FLM-PGOct 18, 2006
135 days to decisionK061549 · Product code: **JHG** · Chemistry
Source: <https://www.510kdatabase.net/k061549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Lecithin/sphingomyelin Ratio (JHG)
Date received	Jun 5, 2006
Decision date	Oct 18, 2006
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Irvine Scientific Sales Co., Inc.
Location	Santa Ana, CA, US
Contact	WENDELL LEE, PHARM. D
510(k) history	40 submissions · 40 cleared · 1997-2017

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