

**K982307 WALLAC NEONATAL LEUCINE TEST KIT MODEL
NL-1000**Feb 2, 1999
216 days to decisionK982307 · Product code: **JNB** · Chemistry
Source: <https://www.510kdatabase.net/k982307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ninhydrin And L-leucyl-l-alanine (fluorimetric), Phenylalanine (JNB)
Date received	Jul 1, 1998
Decision date	Feb 2, 1999
Days to decision	216 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wallac, Inc.
Location	Norton, OH, US
Contact	JANICE K BROWNLEE
510(k) history	2 submissions · 1 cleared · 1999-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982307/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026