

**K131284 GSP NEONATAL BIOTINIDASE KIT**Nov 14, 2013  
192 days to decisionK131284 · Product code: **NAK** · Chemistry  
Source: <https://www.510kdatabase.net/k131284/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Biotinidase (NAK)
Date received	May 6, 2013
Decision date	Nov 14, 2013
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Wallac OY</b>
Location	Finland, FI
Contact	JEANETTE SCHIER-PUGSLEY
510(k) history	22 submissions · 21 cleared · 1992-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131284/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026