

K090123 NEONATAL BIOTINIDASE KIT, MODEL 3018Mar 5, 2010
408 days to decisionK090123 · Product code: **NAK** · Chemistry
Source: <https://www.510kdatabase.net/k090123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Biotinidase (NAK)
Date received	Jan 21, 2009
Decision date	Mar 5, 2010
Days to decision	408 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	PerkinElmer, Inc.
Location	Indianapolis, IN, US
Contact	KAY A TAYLOR
Website	http://www.perkinelmer.com
510(k) history	17 submissions · 15 cleared · 2009-2022

PerkinElmer, Inc. is a global provider of laboratory instruments, reagents, and analytical solutions. The company operates with a manufacturing facility in Indianapolis, US, and specializes in chemistry devices for clinical diagnostics and research applications. PerkinElmer received FDA 510(k) clearances from total submissions between 2009 and 2022. The company's cleared devices focus primarily on neonatal screening and mass spectrometry chemistry kits, along with diagnostic instrumentation. This regulatory record reflects the company's established presence in clinical la...
