

K100101 GSP NEONATALGALT KIT, MODEL 3303-001UJun 11, 2010
149 days to decisionK100101 · Product code: **KQP** · Chemistry
Source: <https://www.510kdatabase.net/k100101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Proc. (qual.), Galactose-1-phosphate Uridyl Transferase (KQP)
Date received	Jan 13, 2010
Decision date	Jun 11, 2010
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	PerkinElmer, Inc.
Location	Indianapolis, IN, US
Contact	KAY 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...
