

**K190335 GSP Neonatal Total Galactose kit**Nov 6, 2019  
265 days to decisionK190335 · Product code: **JIA** · Chemistry  
Source: <https://www.510kdatabase.net/k190335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Methods, Galactose (JIA)
Date received	Feb 14, 2019
Decision date	Nov 6, 2019
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>PerkinElmer, Inc.</b>
Location	Indianapolis, IN, US
Contact	Brian Ciccariello
Website	<a href="http://www.perkinelmer.com">http://www.perkinelmer.com</a>
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...

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