

**K193103 NeoBase 2 Non-derivatized MSMS Kit**Feb 7, 2020  
91 days to decisionK193103 · Product code: **NQL** · Chemistry  
Source: <https://www.510kdatabase.net/k193103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Amino Acids, Free Carnitines And Acylcarnitines Tandem Mass Spectrometry (NQL)
Date received	Nov 8, 2019
Decision date	Feb 7, 2020
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>PerkinElmer, Inc.</b>
Location	Indianapolis, IN, US
Contact	Eva Nalian
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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