FDA 510(k) Premarket Notification

CLEARED

K093916 NEOBASE NON-DERIVATIZED MSMS KIT MODEL 3040-001U

Aug 23, 2010
244 days to decision

K093916 · Product code: **NQL** · Chemistry
Source: https://www.510kdatabase.net/k093916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Amino Acids, Free Carnitines And Acylcarnitines Tandem Mass Spectrometry (NQL)
Date received	Dec 22, 2009
Decision date	Aug 23, 2010
Days to decision	244 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...