

K173568 NeoBase 2 Non-derivatized MSMS KitSep 4, 2018
288 days to decisionK173568 · Product code: **NQL** · Chemistry
Source: <https://www.510kdatabase.net/k173568/>**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	Nov 20, 2017
Decision date	Sep 4, 2018
Days to decision	288 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wallac Oy, Subsidiary of Perkinelmer, Inc.
Location	Waltham, MA, US
Contact	Brian Carney
510(k) history	1 submissions · 1 cleared · 2018-2018

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