

**K173829 NeoLSD MSMS kit**Jul 18, 2018  
212 days to decisionK173829 · Product code: **PQW** · Chemistry  
Source: <https://www.510kdatabase.net/k173829/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-d-galactosidase A (gla) Newborn Screening Test System (PQW)
Date received	Dec 18, 2017
Decision date	Jul 18, 2018
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wallac Oy, A Subsidiary of Perkinelmer</b>
Location	Waltham, MA, US
Contact	Kay A Taylor
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173829/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026