

K190266 NeoLSD MSMS KitMay 3, 2019
84 days to decisionK190266 · Product code: **PQW** · Chemistry
Source: <https://www.510kdatabase.net/k190266/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Alpha-d-galactosidase A (gla) Newborn Screening Test System (PQW) |
| Date received | Feb 8, 2019 |
| Decision date | May 3, 2019 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | PerkinElmer, Inc. |
| Location | Indianapolis, IN, US |
| Contact | Brian Ciccariello |
| 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...
