

**K133652 GSP NEONATAL TOTAL GALACTOSE KIT**Apr 28, 2014  
152 days to decisionK133652 · Product code: **JIA** · Chemistry  
Source: <https://www.510kdatabase.net/k133652/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Enzymatic Methods, Galactose (JIA) |
| Date received         | Nov 27, 2013                       |
| Decision date         | Apr 28, 2014                       |
| Days to decision      | 152 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Wallac Oy, A Subsidiary of Perkinelmer, Inc.</b> |
| Location       | Waltham, MA, US                                     |
| Contact        | JEANETTE SCHIER-PUGSLEY                             |
| 510(k) history | 3 submissions · 3 cleared · 2011-2014               |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133652/> 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 June 7, 2026