

**K071649 NEONATAL TOTAL GALACTOSE KIT**Aug 7, 2008  
416 days to decisionK071649 · Product code: **JIA** · Chemistry  
Source: <https://www.510kdatabase.net/k071649/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Methods, Galactose (JIA)
Date received	Jun 18, 2007
Decision date	Aug 7, 2008
Days to decision	416 days
Third-party review	No
Summary / Statement	Summary
Other names	NEONATAL TOTAL GALACTOSE KIT, MODELS 3029-0010 AND 3029-110B

**APPLICANT**

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Company	<b>Wallac OY</b>
Location	Finland, FI
Contact	CINDY LLOYD
510(k) history	22 submissions · 21 cleared · 1992-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071649/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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