

**K100682 GSP NEONATAL 17A-OH-PROGESTERONE KIT  
MODEL: 3305-001U**Jul 23, 2010  
135 days to decisionK100682 · Product code: **JLX** · Chemistry  
Source: <https://www.510kdatabase.net/k100682/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, 17-hydroxyprogesterone (JLX)
Date received	Mar 10, 2010
Decision date	Jul 23, 2010
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wallac OY</b>
Location	Finland, FI
Contact	KAY TAYLOR
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/k100682/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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