

**K050960 MODIFICATION TO: AUTODELFIA NEONATAL 17A-OH-
PROGESTERONE L KIT**Jul 11, 2005
84 days to decisionK050960 · Product code: **JLX** · Chemistry
Source: <https://www.510kdatabase.net/k050960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, 17-hydroxyprogesterone (JLX)
Date received	Apr 18, 2005
Decision date	Jul 11, 2005
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wallac OY
Location	Finland, FI
Contact	GUNNEL LAAKSONEN
510(k) history	22 submissions · 21 cleared · 1992-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050960/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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