

**K081922 AUTODELFIA NEONATAL 17A-OH-PROGESTERONE
KIT**Apr 16, 2009
283 days to decisionK081922 · Product code: **JLX** · Chemistry
Source: <https://www.510kdatabase.net/k081922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, 17-hydroxyprogesterone (JLX)
Date received	Jul 7, 2008
Decision date	Apr 16, 2009
Days to decision	283 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081922/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026