K081922 AUTODELFIA NEONATAL 17A-OH-PROGESTERONE KIT

CLEARED

Apr 16, 2009
283 days to decision

K081922 · 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