FDA 510(k) Premarket Notification

CLEARED

K100682 GSP NEONATAL 17A-OH-PROGESTERONE KIT MODEL: 3305-001U

Jul 23, 2010
135 days to decision

K100682 · Product code: **JLX** · Chemistry
Source: https://www.510kdatabase.net/k100682/

SUBMISSION DETAILS

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

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