

**K911839 NEONATAL BLOOD SPOT TEST 17-HYDROXPROG
RADIO KIT**

Jun 18, 1991
54 days to decision

K911839 · Product code: **JLX** · Chemistry
Source: <https://www.510kdatabase.net/k911839/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, 17-hydroxyprogesterone (JLX)
Date received	Apr 25, 1991
Decision date	Jun 18, 1991
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pantex, Div. Bio-Analysis, Inc.
Location	Mchenry, IL, US
Contact	NEIL Y CHIAMORI
510(k) history	16 submissions · 16 cleared · 1981-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k911839/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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