

**K060452 ACCUWELL 17-ALPHA-HYDROXYPROESTERONE  
ENZYME IMMUNOASSAY WITH MODELS 6015XX-ECAH**Mar 13, 2007  
385 days to decisionK060452 · Product code: JLX · Chemistry  
Source: <https://www.510kdatabase.net/k060452/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Radioimmunoassay, 17-hydroxyprogesterone (JLX)
Date received	Feb 21, 2006
Decision date	Mar 13, 2007
Days to decision	385 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neo-Genesis</b>
Location	Portland, OR, US
Contact	JANNET BALDWIN
510(k) history	1 submissions · 1 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060452/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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