

**K070921 BIONEXIA HCG PREGNANCY CASSETTE AND  
DIPSTICK TESTS, MODEL 08-HCG AND 02-HCG**Jun 29, 2007  
88 days to decisionK070921 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k070921/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 2, 2007
Decision date	Jun 29, 2007
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Applied Dna Technologies, Inc.</b>
Location	Mission Viejo, CA, US
Contact	Feng-Yu Lee
510(k) history	4 submissions · 4 cleared · 2006-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070921/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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