

**K071030 BIONEXIA HCG PREGNANCY SERUM/URINE  
CASSETTE AND DIPSTICK TESTS, MODELS 08-HCGC AND  
02-HCGC**Jun 29, 2007  
79 days to decisionK071030 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k071030/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 11, 2007
Decision date	Jun 29, 2007
Days to decision	79 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/k071030/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 24, 2026