

**K834270 ORTHO ENZYME IMMUNOASSAY HOME PREG.TEST**May 14, 1984  
158 days to decisionK834270 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k834270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Dec 8, 1983
Decision date	May 14, 1984
Days to decision	158 days
Third-party review	No

**APPLICANT**

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Company	<b>Advanced Care Products</b>
Location	Walker, MI, US
510(k) history	6 submissions · 6 cleared · 1984-1995

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