

**K953581 FIRST RESPONSE OVULATION PREDICTOR TEST**Oct 3, 1995  
63 days to decisionK953581 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k953581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Aug 1, 1995
Decision date	Oct 3, 1995
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Armkel, LLC</b>
Location	Mchenry, IL, US
Contact	Maureen Garner
510(k) history	68 submissions · 68 cleared · 1979-2004

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