

**K973310 TBD\* ONE-STEP OVULATION PREDICTOR TEST**Oct 27, 1997  
54 days to decisionK973310 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k973310/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Sep 3, 1997
Decision date	Oct 27, 1997
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973310/> 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 29, 2026