

**K890645 ESTRADIOL MAIACLONE RADIOIMMUNOASSAY KIT**Mar 8, 1989  
28 days to decisionK890645 · Product code: **CHP** · Chemistry  
Source: <https://www.510kdatabase.net/k890645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Feb 8, 1989
Decision date	Mar 8, 1989
Days to decision	28 days
Third-party review	No

**APPLICANT**

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Company	<b>Serono-Baker Diagnostics, Inc.</b>
Location	Winchester, VA, US
Contact	R. E TOMALESKY
510(k) history	23 submissions · 23 cleared · 1988-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k890645/>; 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