

**K912318 ESTRADIOL SEROZYME ENZYME IMMUNO (MAG SOLID-PHASE)**Jul 25, 1991  
62 days to decisionK912318 · Product code: **CHP** · Chemistry  
Source: <https://www.510kdatabase.net/k912318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	May 24, 1991
Decision date	Jul 25, 1991
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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