

**K894175 SRI HUMAN CHORIONIC GONADOTROPIN  
IMMUNOENZ ASSAY**Dec 19, 1989  
187 days to decisionK894175 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k894175/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jun 15, 1989
Decision date	Dec 19, 1989
Days to decision	187 days
Third-party review	No

**APPLICANT**

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Company	<b>Serono-Baker Diagnostics, Inc.</b>
Location	Winchester, VA, US
Contact	TOMALESKY, PHD
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/k894175/>; 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