

**K970643 VITROS IMMUNODIAGNOSTICS PRODUCTS  
ESTRADIOL REAGENT PACK(GEM. 1050)/ESTRADIOL  
CALIBRATORS (GEM.C050)**Mar 18, 1997  
26 days to decisionK970643 · Product code: **CHP** · Chemistry  
Source: <https://www.510kdatabase.net/k970643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Feb 20, 1997
Decision date	Mar 18, 1997
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Johnson &amp; Johnson Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	ANN M QUINN
510(k) history	33 submissions · 33 cleared · 1995-1998

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