

**K964982 VITROS IMMUNODIAGNOSTICS PRODUCTS LH
REAGENT PACK (GEM.1055) AND LH CALIBRATORS
(GEM.CO55)**Feb 20, 1997
70 days to decisionK964982 · Product code: **CEP** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Dec 12, 1996
Decision date	Feb 20, 1997
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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