

**K964720 VITROS IMMUNODIAGNOSTICS PRODUCTS FSH
REAGENT PACK (GEM. 1005) FSH CALIBRATORS (GEM.C005)**Feb 4, 1997
71 days to decisionK964720 · Product code: **CGJ** · Chemistry
Source: <https://www.510kdatabase.net/k964720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Nov 25, 1996
Decision date	Feb 4, 1997
Days to decision	71 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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