

**K965048 VITROS IMMUNODIAGNOSTICS PRODUCTS RE
CONTROLS (GEM.5015)**Jan 27, 1997
40 days to decisionK965048 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k965048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Dec 18, 1996
Decision date	Jan 27, 1997
Days to decision	40 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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