

**K974644 VITROS IMMUNODIAGNOSTIC PRODUCTS RANGE
VERIFIERS**Jan 13, 1998
32 days to decisionK974644 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k974644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 12, 1997
Decision date	Jan 13, 1998
Days to decision	32 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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