

**K973030 VITROS IMMUNODIAGNOSTICS PRODUCTS/CK-MB
REAGENT PACK(GEM.1300)/CK-MB CALIBRATORS
(GEM.C300)**Sep 4, 1997
21 days to decisionK973030 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k973030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Aug 14, 1997
Decision date	Sep 4, 1997
Days to decision	21 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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