

K970894 VITROS IMMUNODIAGNOSTICS PRODUCTS TOTAL B-HCG REAGENT PACK (GEM.1075), TOTAL B-HCG CALIBRATORS (GEM.C075)Apr 14, 1997
34 days to decisionK970894 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k970894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Mar 11, 1997
Decision date	Apr 14, 1997
Days to decision	34 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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