

K974009 PS-UNIT CASSETTE/SERUM AND URINE COMBO HCGMar 13, 1998
143 days to decisionK974009 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k974009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 21, 1997
Decision date	Mar 13, 1998
Days to decision	143 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	International Newtech Development, Inc.
Location	Richmond, B.C., CA
Contact	BENNY WANG
510(k) history	8 submissions · 8 cleared · 1995-2000

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