

**K963133 PS-UNIT CASSETTE/SERUM HCG**Nov 18, 1996  
98 days to decisionK963133 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k963133/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 12, 1996
Decision date	Nov 18, 1996
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>International Newtech Development, Inc.</b>
Location	Richmond, B.C., CA
Contact	JESSE ZHU
510(k) history	8 submissions · 8 cleared · 1995-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963133/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026