

K911826 IMMUNOCARD HCG ONE STEP (I-S) TEST KITJul 19, 1991
86 days to decisionK911826 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k911826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 24, 1991
Decision date	Jul 19, 1991
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Disease Detection International, Inc.
Location	Irvine, CA, US
Contact	SIEGFRIED KRUTZIK
510(k) history	20 submissions · 20 cleared · 1988-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911826/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026