FDA 510(k) Premarket Notification

K062361 INNOVACON HCG UKTRA TEST DEVICE

CLEARED

Oct 23, 2006
70 days to decision

K062361 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k062361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 14, 2006
Decision date	Oct 23, 2006
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innovacon, Inc.**
Location	San Diego, CA, US
Contact	EDWARD TUNG
510(k) history	3 submissions · 3 cleared · 2006-2007