FDA 510(k) Premarket Notification

K063673 INNOVACON FLIPCARD FECAL OCCULT BLOOD TEST DEVICE

CLEARED

Mar 5, 2007
84 days to decision

K063673 · Product code: **KHE** · Hematology
Source: https://www.510kdatabase.net/k063673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Dec 11, 2006
Decision date	Mar 5, 2007
Days to decision	84 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