

**K063693 FORSURE ONE STEP FECAL OCCULT BLOOD (FOB)
SCREEN CARD TEST**May 11, 2007
149 days to decisionK063693 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k063693/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Dec 13, 2006
Decision date	May 11, 2007
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Bay Bioresearch Co. , Ltd.
Location	Carlsbad, CA, US
Contact	RODRIGO BERLIE
510(k) history	1 submissions · 1 cleared · 2007-2007

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