

K110309 FOB ONE STEP RAPID TESTSep 14, 2011
224 days to decisionK110309 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k110309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Feb 2, 2011
Decision date	Sep 14, 2011
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orient Gene Biotech
Location	East Stroudsburg, PA, US
Contact	Gary Lehnus
510(k) history	1 submissions · 1 cleared · 2011-2011

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