

K173212 Instant-view-PLUS immunochemical Fecal Occult Blood TestFeb 15, 2018
136 days to decisionK173212 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k173212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Oct 2, 2017
Decision date	Feb 15, 2018
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Scientific Designs, Inc.
Location	Poway, CA, US
Contact	Wen Hua Fan
510(k) history	43 submissions · 43 cleared · 1999-2018

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