

K162333 Wondfo One Step Fecal Occult Blood (FOB) TestMay 14, 2017
265 days to decisionK162333 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k162333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Aug 22, 2016
Decision date	May 14, 2017
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Bin Chen
510(k) history	43 submissions · 43 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Joe Shia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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