FDA 510(k) Premarket Notification

K162333 Wondfo One Step Fecal Occult Blood (FOB) Test

CLEARED

May 14, 2017
265 days to decision

K162333 · 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