FDA 510(k) Premarket Notification

CLEARED

K021423 INSTANT-VIEW FECAL OCCULT BLOOD RAPID TEST

Jun 17, 2002
45 days to decision

K021423 · Product code: **KHE** · Hematology
Source: https://www.510kdatabase.net/k021423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Reagent, Occult Blood (KHE)
Date received	May 3, 2002
Decision date	Jun 17, 2002
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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