

K041202 HEMOSURE ONE-STEP FECAL OCCULT BLOOD TESTAug 12, 2004
97 days to decisionK041202 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k041202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	May 7, 2004
Decision date	Aug 12, 2004
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.H.P.M., Inc.
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	14 submissions · 14 cleared · 2001-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041202/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026