

K041297 POLYMEDCO OC LIGHT FOBT TESTAug 12, 2004
90 days to decisionK041297 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k041297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	May 14, 2004
Decision date	Aug 12, 2004
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Polymedco, Inc.
Location	Cortlandt Manor, NY, US
Contact	HELEN LANDICHO
510(k) history	19 submissions · 19 cleared · 1992-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041297/> 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 June 18, 2026