FDA 510(k) Premarket Notification

K040146 INTERLAB ACID HEMOGLOBIN ELECTROPHORESIS TEST SYSTEM

CLEARED

May 4, 2004
103 days to decision

K040146 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k040146/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Jan 22, 2004
Decision date	May 4, 2004
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Interlab S.R.L.**
Location	East Stroudsburg, PA, US
Contact	Gary Lehnus
510(k) history	4 submissions · 4 cleared · 2003-2006