FDA 510(k) Premarket Notification

K934274 HEMOLAB HEPARICHROM ASSAY

CLEARED

May 6, 1994
248 days to decision

K934274 · Product code: **KFF** · Hematology
Source: https://www.510kdatabase.net/k934274/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Aug 31, 1993
Decision date	May 6, 1994
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomerieux Vitek, Inc.**
Location	Hazelwood, MO, US
Contact	CHERYL WINTERS-HEARD
510(k) history	49 submissions · 49 cleared · 1992-1998