FDA 510(k) Premarket Notification

K933010 BIOMERIEUX HEMOLAB COFAC VIII

CLEARED

Sep 15, 1993
86 days to decision

K933010 · Product code: **GJT** · Hematology
Source: https://www.510kdatabase.net/k933010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jun 21, 1993
Decision date	Sep 15, 1993
Days to decision	86 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