FDA 510(k) Premarket Notification

K934326 MULTIFIBREN U

CLEARED

Apr 19, 1994
228 days to decision

K934326 · Product code: **KQJ** · Hematology
Source: https://www.510kdatabase.net/k934326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Sep 3, 1993
Decision date	Apr 19, 1994
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Behring Diagnostics, Inc.**
Location	Mchenry, IL, US
Contact	LORI BARANAUSKAS
510(k) history	145 submissions · 145 cleared · 1976-1997