FDA 510(k) Premarket Notification

K925863 SPUNCRIT

CLEARED

Feb 5, 1993
78 days to decision

K925863 · Product code: **GKG** · Hematology
Source: https://www.510kdatabase.net/k925863/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Centrifuge, Hematocrit (GKG)
Date received	Nov 19, 1992
Decision date	Feb 5, 1993
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**bioMerieux, Inc.**
Location	Mchenry, IL, US
Contact	ROD KATZER
510(k) history	251 submissions · 250 cleared · 1983-2026