FDA 510(k) Premarket Notification

K964963 LYPHOCHEK COAGULATION CONTROL

CLEARED

Feb 20, 1997
71 days to decision

K964963 · Product code: **GGN** · Hematology
Source: https://www.510kdatabase.net/k964963/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Dec 11, 1996
Decision date	Feb 20, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad**
Location	Mchenry, IL, US
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Website	http://www.bio-rad.com
510(k) history	319 submissions · 319 cleared · 1976-2017