FDA 510(k) Premarket Notification

K984130 COAGULATION CONTROL LEVEL 2 (ABNORMAL)

CLEARED

Dec 1, 1998
13 days to decision

K984130 · Product code: **GGC** · Hematology
Source: https://www.510kdatabase.net/k984130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Nov 18, 1998
Decision date	Dec 1, 1998
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pacific Hemostasis**
Location	Mchenry, IL, US
Contact	MARK ELLIS
510(k) history	29 submissions · 29 cleared · 1978-2000