FDA 510(k) Premarket Notification

K974343 DADE INNOVIN

CLEARED

Jul 22, 1998
245 days to decision

K974343 · Product code: **GJS** · Hematology
Source: https://www.510kdatabase.net/k974343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Nov 19, 1997
Decision date	Jul 22, 1998
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dade Intl., Inc.**
Location	Deerfield, IL, US
Contact	RADAMES RIESGO
510(k) history	30 submissions · 30 cleared · 1995-1998