K010494 SYSMEX AUTOMATED COAGULATION ANALYZER, MODEL CA-1500

CLEARED

May 1, 2001
70 days to decision

K010494 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k010494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 20, 2001
Decision date	May 1, 2001
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dade Behring, Inc.**
Location	Newark,, DE, US
Contact	RADAMES RIESGO
510(k) history	343 submissions · 343 cleared · 1978-2010