FDA 510(k) Premarket Notification

K931149 CA-1000 AUTOMATED COAGULATION ANALYZER

CLEARED

Nov 3, 1993
240 days to decision

K931149 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k931149/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Mar 8, 1993
Decision date	Nov 3, 1993
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Toa Medical Electronics USA, Inc.**
Location	Mchenry, IL, US
Contact	JEME WALLACE
510(k) history	33 submissions · 33 cleared · 1978-1994