FDA 510(k) Premarket Notification

K972260 CS-400 COAGULATION ANALYZER SYSTEM (A1208)

CLEARED

Oct 20, 1997
125 days to decision

K972260 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k972260/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jun 17, 1997
Decision date	Oct 20, 1997
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sigma Diagnostics, Inc.**
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002