CLEARED

K233790 ACL TOP 970 CL

Dec 29, 2023
31 days to decision

K233790 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k233790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Nov 28, 2023
Decision date	Dec 29, 2023
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Instrumentation Laboratory**
Location	Lexington, MA, US
Contact	Nikita Malladi
510(k) history	3 submissions · 3 cleared · 2008-2023