FDA 510(k) Premarket Notification

K032952 AIACT KIT

CLEARED

Dec 12, 2003
81 days to decision

K032952 · Product code: **JBP** · Hematology
Source: https://www.510kdatabase.net/k032952/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Whole Blood Clotting Time (JBP)
Date received	Sep 22, 2003
Decision date	Dec 12, 2003
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sienco, Inc.**
Location	Broomfield, CO, US
Contact	BARBARA DEBIASE
510(k) history	5 submissions · 5 cleared · 1995-2023