

K032952 AIACT KITDec 12, 2003
81 days to decisionK032952 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032952/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026